PSJ17 Exh 84

2010 Brand Plan

Cephalon

FENTORA™
fentanyl buccal tablet

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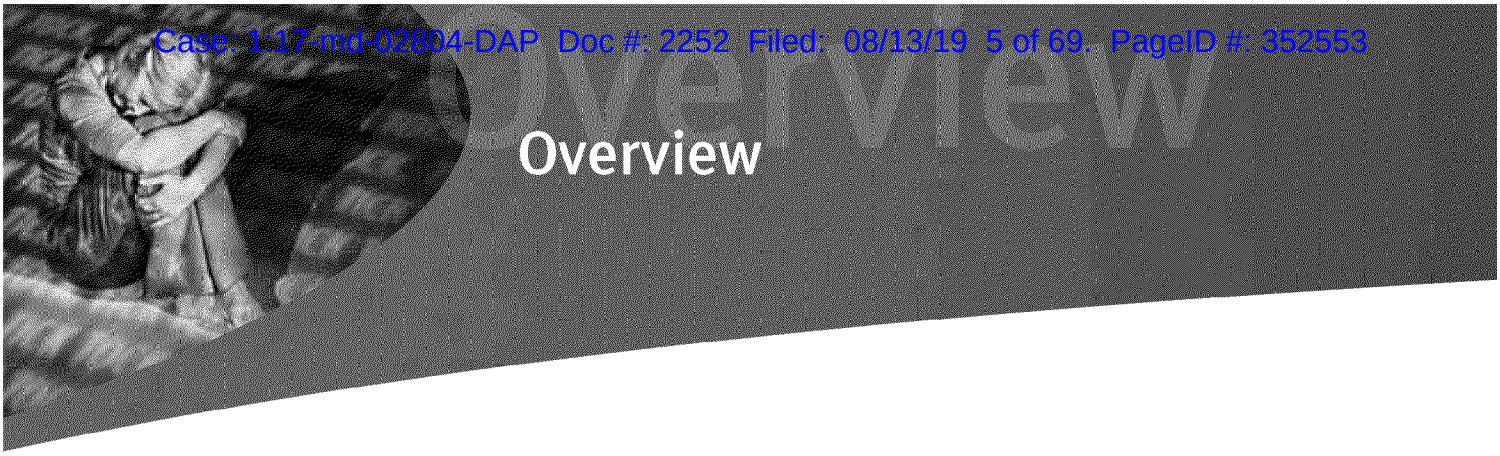
FENTORA®
fentanyl buccal tablet



Overview

FENTORA 2010 Brand Plan

Content provided by:

Clinical, HCS, Legal, Marketing, Market Research, Public Relations, Regulatory, Sales, Sales Operations, Medical, Sales Training, SciCom, Strategic Planning, and AMFE

This document is based on the known product situation as of June 2009. It includes strategies and tactics based on assumptions with regard to regulatory outcomes, product enhancements, and clinical development plans. Sales and Marketing promotion is currently limited to the indication listed in the product's package insert as of September 1, 2008. Any reference to breakthrough pain (BTP) in the context of strategy/promotion refers to *Breakthrough pain in opioid tolerant patients with cancer.*

This is an internal planning document and is not intended for promotional use, but for review and/or reference of internal stakeholders.

Overview

FENTORA 2010 Brand Plan

Overview

The *FENTORA* Marketing Team is pleased to provide you with the 2010 *FENTORA* Brand Plan. This document will provide in-depth coverage on the disease state, the marketplace, competition, product features and performance, key issues faced, and finally, the *FENTORA* business strategy and overview of 2010 tactics.

The National Pharmaceutical Council estimated that 50 million Americans suffer from chronic pain.[1] Chronic pain consists of 2 components: persistent pain and BTP.[1] While not all chronic pain patients suffer from BTP, prevalence studies have found that an estimated 51% to 89% of patients experience BTP episodes. BTP has been defined as a transitory exacerbation, or flare, of a moderate to severe pain that occurs in patients on chronic opioid therapy with otherwise stable persistent pain. BTP escalates to a maximum intensity in as little as 3 minutes, often strikes without warning, and typically occurs about 4 times per day.[2,3]

The distinct characteristics of BTP make it a challenge to manage. There are no validated assessment tools and no clear guidelines on optimal treatment regimens. Market research findings show that adjusting the long-acting opioids (LAOs) and/or adding short-acting opioids (SAOs) is the typical course of action when treating a BTP episode. The clinical profile of SAOs suggests that these may not be optimal treatment options, as the onset of analgesia is 30 to 45 minutes. Adding a rapid-onset opioid (ROO) like *FENTORA* is typically the last course of action, even though it is designed to match the early onset of a BTP episode.

FENTORA is a medication indicated for the management of BTP in opioid tolerant patients with cancer. Launched in 2006 (patent expiry 2019), *FENTORA* is the first and only buccal tablet that utilizes an OraVescent® reaction to provide onset of analgesia in as early as 15 minutes, matching the characteristics of BTP.

FENTORA competes in the SAO market space. The SAO category is made up of pure, combination, and ROOs (considered a subclass of the SAOs). The SAO marketplace is saturated with low-cost generics which provide healthcare professionals (HCPs) an ease of prescribing due to minimal reimbursement hurdles. Additionally, prescribers have a comfort level and familiarity with prescribing SAOs and perceive them to have minimal risk to patients. The challenge *FENTORA* faces is that based on the reasons above, prescribers do not see a meaningful value of prescribing it versus SAOs for BTP.

The ROO subclass is currently made up of Actiq®, its 3 generics,[a] and the recently approved Onsolis™ (fentanyl buccal soluble film). These are all fentanyl-based products with different delivery systems. *FENTORA* is disadvantaged in this class due to its lack of comparable high dosage strength. However, *FENTORA* and Actiq/oral transmucosal fentanyl citrate (OTFC) are available through retail distribution, whereas Onsolis is only available through a restrictive distribution system (specialty pharmacy). There are also a number of ROOs in development. These ROOs may be unintentional allies to *FENTORA*, as they will likely aid in the awareness and education around BTP as well as appropriate patient selection. However, there are foreseeable disadvantages to *FENTORA*, such as available dosage strengths, potential for earlier onset of analgesia, and alternate routes of administration, which future competitors may exploit.

[a] A third generic was approved October 2009 and is expected to launch Q1 2010 with an extensive risk management plan.

2010 will be a pivotal year for rebuilding the foundation for *FENTORA*, and a number of key events are anticipated. These include the launch of the *FENTORA* Risk Evaluation and Mitigation Strategies (REMS; SECURE Access™), the availability of head-to-head data (*FENTORA* vs OxyIR), and dosing and administration label enhancements (sublingual route of administration and high dose).

A significant market dynamic that all opioids will encounter is the requirement of a risk minimization plan. The regulatory authorities have mandated REMS. These programs must incorporate safe use elements that are measurable and effective. The REMS programs for *FENTORA* as well as for Actiq/OTFC are on an aggressive regulatory clock and will most likely be required to implement an access program substantially earlier than the LAOs and SAOs. This mandated program will have an impact on our prescribers. The nature and degree of this impact is not yet possible to determine.

The *FENTORA* 2010 brand strategy will focus on competitive issues, reimbursement challenges, and the pending REMS program currently being reviewed by the FDA. In order to achieve success in 2010, there are 3 strategic goals to be accomplished:

1. *Differentiate with a compelling value proposition*
   Ensure prescribers recognize that *FENTORA* is an ideal option for those appropriate patients with cancer who are suffering from BTP episodes, because *FENTORA* matches the temporal characteristics of BTP.
2. *Reduce barriers to FENTORA treatment*
   Reinvigorate the prescribers' willingness to navigate the reimbursement process so that appropriate patients have access to *FENTORA*.

   Managed care recognizes the value of *FENTORA* for select patients.
3. *Flawlessly execute the SECURE Access Program*
   Prescribers enroll and participate in the SECURE Access Program.

In order to compete with SAOs used for the treatment of BTP and with new ROO competitors, it will be important for Cephalon to provide appropriate support for *FENTORA*. This will include a dedicated sales force effort, nonpersonal promotion, medical education, public relations outreach, and the implementation of a robust publication plan.

With the solid strategies set forth in this document and the successful implementation of the tactical plan, it is estimated that *FENTORA* will generate $140MM in 2010.

FENTORA®
fentanyl buccal tablet

Executive Summary

FENTORA Profile

Product Description: Fentanyl incorporated into the OraVescent® drug delivery platform

Indication: Breakthrough pain (BTP) in opioid tolerant patients with cancer

Dosage: 100-, 200-, 400-, 600-, 800-mcg tablets

Administration: Placement on the buccal mucosa

Safety: Similar AE profile and abuse potential to C-II opioids, REMS

Efficacy: 15-minute onset and up to 60-minute duration

Key Events

Launched: September 2006

SECURE Access Program (REMS): Estimated approval in 2010

Response to CRL for sNDA: Q4 2010

Patent Expiration: 2019 Method of Use: #6,200,604

Performance

	2007	2008	2009
Prescriptions	89,373	74,814	FC ~ 65,000
Dollars (actual)	$152,076,558	$174,255,930	FC – $169,083,000 (~$135,000,000 net)
% to Objective	99%	100%	~97%
Exit Market Share	27.3%	26.9%	~29.2%

FC, forecast.

Executive Summary

Market Overview (as defined by Cephalon)

Opioid Category	Value			Volume		
	6/09 MAT ($ - MM)	6/09 MAT (%)	6/09 MAT – 6/08 MAT Δ	6/09 MAT (TRx MM)	6/09 MAT (%)	6/09 MAT – 6/08 MAT Δ
ROOs	$563	8%	-12%	250K	<1%	-18%
Pure SAOs[a]	$920	13%	1%	13	6%	11%
Combo SAOs	$1,214	17%	5%	166	81%	5%
LAOs	$5,067	70%	14%	26	13%	3%
Total opioids	$7,202	100%	10%	205	100%	5%

Source: IMS data; NPA and NSP.
[a] Pure SAOs include ROOs.

Market Size and Growth

Opioid market is large and continues to grow in value and volume

LAOs dominate market value

Combination SAOs dominate market volume

Pure SAOs experience growth in volume but a minimal increase in value due to generic OTFCs

ROOs have declined in volume and value growth due to limited promotion, generics, and increased managed care hurdles

2009 *FENTORA* (forecast): $174MM

Market Drivers

Increase in number of chronic pain patients continues to drive opioid prescriptions

Market Threats

Competition from SAO, branded ROO (Onsolis™ [fentanyl buccal soluble film]), and generic OTFC

MCOs continue to limit access to ROO via prior authorizations and step edits

In general, there is a concern that persists around abuse, addiction, and diversion for opioids

Opioid Market Competitive Analysis

Company	2008 US Pain Sales	Growth (+/-)	Key Pain Products Promoted	Sales Force Size	Products in Development
Purdue	$2.3B	+115%	OxyContin®[a] MS Contin® OxyIR® Ryzolt®	250	• Oxycontin CR • BTDS (transdermal buprenorphine)
King (Acquired Alpharma 12/08)	$1.1B	+20%	Avinza®[b] Kadian®[c] Skelaxin®[c] Flector® Patch[b] Embeda®[c]	Total: 669 Hosp: 100 Spec: 407 Pain: 157 Managed Care: 20	• Acurox • Remoxy abuse-resistant • Oxycodone NT abuse-resistant
Endo	$1.4B	+21.3%	Lidoderm®[b] Opana IR®[b] Opana ER®[b] Percocet®[c]	Total: 755 Pharma: 360 Specialty: 395	• Topical ketoprofen patch • Frova (new indication) • Axomadol
MEDA	$56MM	+65%	SOMA®[b] Onsolis[c]	Total: 501 PCP: 426 Specialty: ~110	
ProStraken	Establishing US management team	N/A	No pain products Sancuso® (chemo-induced nausea and vomiting)	Building sales team of 67	• Abstral® (NDA submitted October 2009)
J&J	$465MM	+5%	Ultram ER®[b] Nucynta™[c] Nucynta ER™[c]	Total: 3,197 Pain: 550	

Source: IMS NSP; Dominion Group Competitive Intelligence Report Sept 2009; SDI, Sales Force Structures and Strategies 2Q 2009.

[a] Promotional Sales Force information not available for Purdue.

[b] Represents that the product was promoted during 2Q 2009.

[c] Represents that the product was not promoted during 2Q 2009.

Executive Summary

Approved ROO Competitive Profile Comparison

Key Attributes	*FENTORA* Buccal Tablet	Onsolis Buccal Film	Actiq/OTFC
Indication	BTP in CA pts (99-14)	BTP in CA pts	BTP in CA pts
Future Indication	BTP in non-CA patients; sNDA pending	BTP in non-CA patients; clinical development	
Active Ingredient	Fentanyl	Fentanyl	Fentanyl
Onset	15 min	15 min	15 min
Duration	60 min	60 min	60 min
Absolute Bioavailability	65%	70%	47%
Dosage	100-800 mcg	200-1200 mcg	200-1600 mcg
Safety	Comparable	Comparable	Comparable
Mucosal Irritation	Low	Minimal/none	Dental caries
Taste	"Baking soda"	Mint	Sweet
Clinical Data	Breadth of clinical database and publications	Limited clinical database, only abstracts and posters	Moderate
Sales Force Size	110 PCS 2-product calls	~110 Specialty Primary position expected	Not promoted
Targets	~6000	High ROO prescribers	NA

Sources: BioDelivery Science International April 25, 2007; Press release Onsolis™ Fentanyl Demonstrates Substantial Transmucosal Delivery in Absolute Bioavailability Study; Press release May 14, 2007, BDSI Announces Positive Key Secondary Endpoint Results for Onsolis™ Fentanyl; Press release December 17, 2007; BioDelivery Science International November 19, 2008; Press release: BioDelivery Science Remains on Schedule for December Onsolis Resubmission Following Meeting with FDA; Webcast: November 7, 2008; BioDelivery Sciences to Meet with FDA to Finalize Proposed REMS for Onsolis. Actiq PI. *FENTORA* PI, October 2007; Onsolis PI, July 2009.

mmary

FENTORA Profile

Advantages vs Actiq/OTFC:

- Greater absolute bioavailability (65% vs 47%)
- More discreet and user-friendly drug delivery
- Simplified titration scheme

Advantages vs Onsolis:

- Market experience
- More extensive clinical database
- Retail versus specialty distribution
- Buccal tablet with potential alternative route of administration (sublingual)

Key Issues for 2010

1. The clinically meaningful value of *FENTORA* is not seen by HCPs	• Belief that SAOs are sufficient in the treatment of BTP • Benefits of a ROO/*FENTORA* are not valued by most prescribers • HCPs often do not recognize patients who would most benefit from *FENTORA*
2. Multiple barriers to writing *FENTORA* perceived by HCPs	• Managed care restrictions/hurdles • High patient "out-of-pocket" cost • Fears and perceptions of increased risk
3. Limited HCP awareness, acceptance, and endorsement of opioid REMS	• Prescriber base is not REMS savvy • Perception of increased burden to HCP and office staff • Concerns around perceived increased liability

Overall Business Strategy

Enhance prescriber understanding of the value *FENTORA* offers to opioid tolerant patients with BTP, motivating prescribers to address payer access hassles and enroll/participate in SECURE access.

Executive Summary

2010 Brand Objectives: *Rebuilding the Foundation*

2010 Mission ⇨ Rebuilding the foundation

Brand Objectives ⇨

Quantitative:
- $140MM
- Retain ~85% of core prescriber base
- Core prescriber productivity ~3 Rx/month

Qualitative:
- Increased understanding, recognition, and communication of BTP among prescribers and patients
- Improved assessment of BTP and optimal treatment with *FENTORA* for appropriate patients
- Effective stakeholder enrollment and participation in SECURE Access

Key Issues ⇨

- HCPs do not see the clinically meaningful value of *FENTORA*
- HCPs perceive too many barriers to writing *FENTORA*
- Limited HCP awareness, acceptance, and endorsement of opioid REMS

Key Strategic Imperatives ⇨

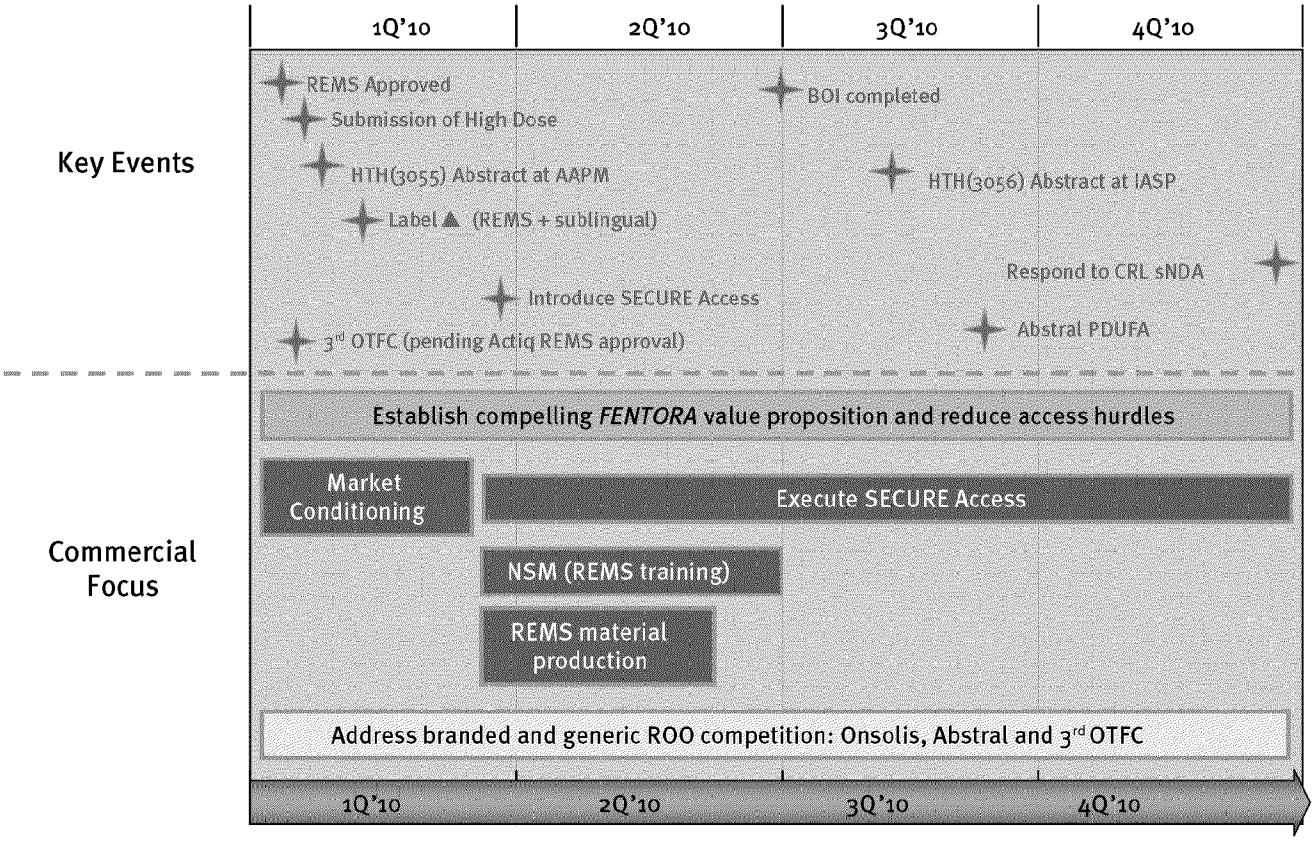
- Differentiate with a compelling value proposition
- Reduce barriers to *FENTORA* treatment
- Flawlessly execute SECURE Access

Strategies ⇨

Differentiate with a compelling value proposition	Reduce barriers to *FENTORA* treatment	Flawlessly execute SECURE Access
Enhance HCP–patient dialogue	Elevate importance of appropriate treatment and outcomes to all key stakeholders	Drive positive perception and early enrollment
Establish functionality as benefit of appropriate BTP treatment	Enhance reimbursement support	Execute training appropriate to each stakeholder
Differentiate *FENTORA* from SAOs/Onsolis	Segment payer market to drive targeted efforts	Generate program advocacy

Key Assumption (based on discussions/agreements with the FDA)

2010 will be a pivotal year for rebuilding the foundation for *FENTORA*. As such, a number of key events are anticipated. These include the launch of the *FENTORA* REMS program (SECURE Access), the availability of head-to-head data (*FENTORA* vs OxyIR), and dosing and administration label enhancements (sublingual route of administration and high dose).



Executive Summary

Financial Objectives

Total Revenue: $140MM

TRxs: 48,000

TRx Exit Share: 25%

Total Marketing Budget: $20MM

REMS: ~ $ 7MM

Advertising and promotion: ~ $ 13MM

Sales Force Allocation: 110 representatives

Assumptions

SECURE Access approved as submitted

Retail pharmacy distribution

FENTORA prescribing impacted by REMS

Opioid non-tolerant patients excluded (~20%)

Opioid class follow similar/same REMS requirements

SECURE Access investment leveraged for success

Challenges to Assumptions

REMS impact

Process disruption from program

Prescribing shifts to alternative opioids that do not have the burdensome perception of a REMS program

Loss from patients not meeting opioid tolerant criteria (~20%)

Competitive impact

Increased voice in BTP market

High-dose advantage over *FENTORA*

Specialty pharmacy distribution

FENTORA®
fentanyl buccal tablet

Situation Analysis

Data show that BTP occurs frequently in patients with chronic pain (both cancer- and non–cancer-related) whose baseline pain is characterized as being under control. BTP can strike a patient quickly and without warning, escalating to its peak intensity in just minutes, with a median duration of 30 minutes in patients with cancer.

There are 4 general types of BTP[4]:

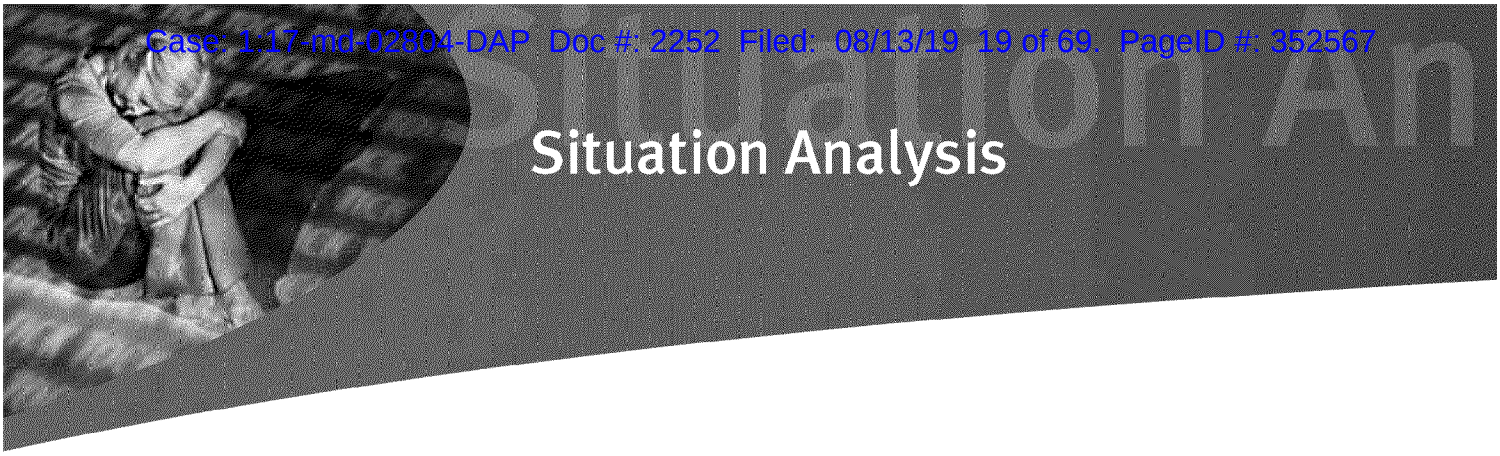
1. Incident/predictable, in which there is a consistent temporal causal relationship between the pain and specific motor activity (eg, getting out of bed or walking).
2. Incident/unpredictable, in which such a relationship is inconsistent (eg, pain when sneezing or with bladder spasm).
3. Idiopathic, in which the cause of the pain is unknown.
4. End-of-dose failure, which occurs before a scheduled dose of an ATC analgesic is administered. This type has a more gradual onset and longer duration and is usually treated by increasing the ATC dose or reducing the interval between doses.

BTP Prevalence and Characteristics

	Cancer BTP (N=63)[2,5]	Noncancer BTP (N=228)[6]
Prevalence	64% to 89%[2,5]	74%
Median episodes/day	4 to 7[2,5]	2
Time to peak intensity	43% in 3 mins	50% in 5 mins
Median duration	30 mins	60 mins
Incident-related	55%	92%
Pathophysiology	Somatic (33%) Visceral (20%) Neuropathic (27%) Mixed (20%)	Somatic (38%) Visceral (4%) Neuropathic (18%) Mixed (40%)

Awareness and Understanding of BTP

While BTP has been an identified disease state for nearly 20 years, prescribers still have limited awareness and understanding of it, limited tools to accurately assess BTP, and no clear guidelines around optimal treatment. Additionally, market research suggests there is a communication gap between the prescriber and the patient when it comes to the discussion around BTP due to a difference of language used. As a result of this gap, it has been challenging for physicians and patients to clearly identify, diagnose, and manage BTP.



Situation Analysis

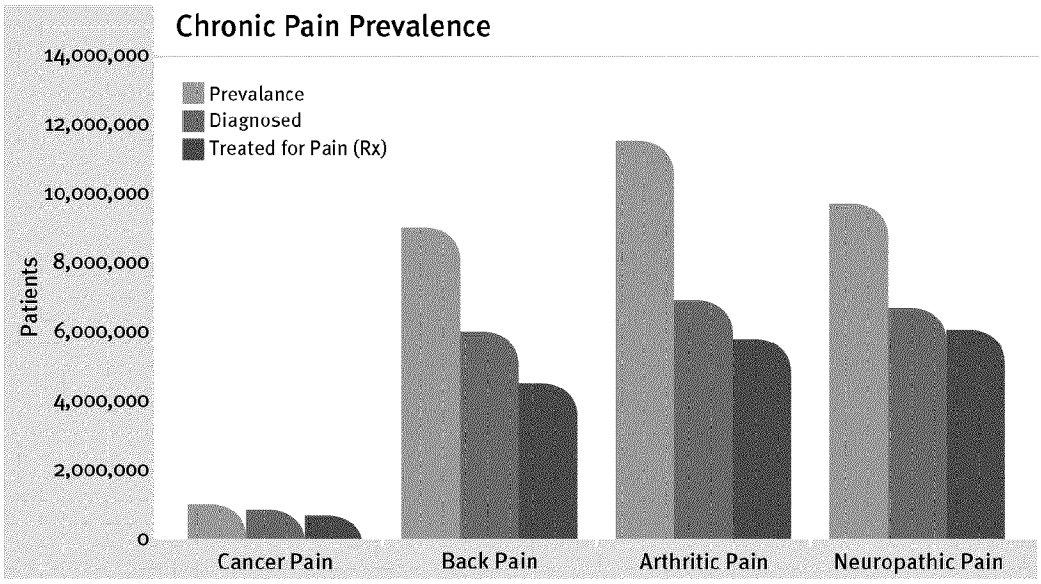
Market Assessment

Disease Background

Chronic Pain

Chronic pain is a common malady in the United States. Chronic pain has been defined as pain that persists beyond the normal healing time (often defined as >3 months). The National Pharmaceutical Council estimated that 50 million Americans suffer from chronic pain per year.

The chart below presents derived estimates of prevalence, diagnosis rates, and treated patients by leading disease states.

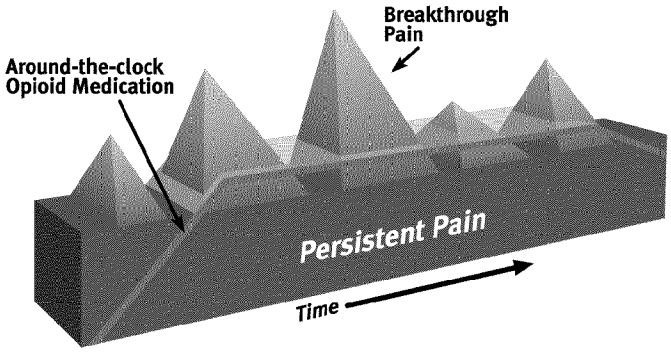


Source: Cephalon Market Research.

Breakthrough Pain

Within chronic pain there are 2 components: persistent pain and breakthrough pain (BTP).

Persistent pain is pain that lasts all day and is typically treated with an around-the clock opioid medication. BTP has been defined as a transitory exacerbation, or flare, of a moderate to severe pain that occurs in patients on chronic opioid therapy with otherwise stable persistent pain.[2,3]



Impact of BTP[7]

Limited studies have assessed the cost and benefit elements associated specifically with BTP, and none have presented a pharmacoeconomic analysis for BTP. Current evidence suggests that BTP has significant negative effects (physical, emotional, and financial) on patients, caregivers, and the healthcare system. BTP is associated with decreased functional status, increased levels of anxiety and depression, dissatisfaction with treatment, and poor medical outcomes.

In 2002, Fortner et al published a study of outpatients with cancer. The study suggested that cancer patients with BTP had higher costs associated with hospitalizations, ER visits, and doctor visits, compared to cancer patients without BTP.[8]

Cancer Pain Patients' Pain-Related Visits and Hospitalizations (Total Survey Sample N=1000)

	Patients w/BTP (n=160)	Patients w/o BTP (n=89)
Hospital stays per year	1.0	0.4
Length of hospital stay, days	7.1	4.1
ER visits per year	1.3	0.5
Outpatient doctor visits	4.2	0.6
Annual cost per patient	$12,000	$2,400

In 2003, another study by Fortner et al concluded that cancer patients with BTP had higher direct and indirect costs.[9]

Cancer Outpatients With Cancer-Related Pain (69% of 144 Surveyed Patients)

	Patients w/BTP	Patients w/o BTP
Mean monthly direct medical costs	$1,080	$750
Mean monthly indirect costs	$88	$53

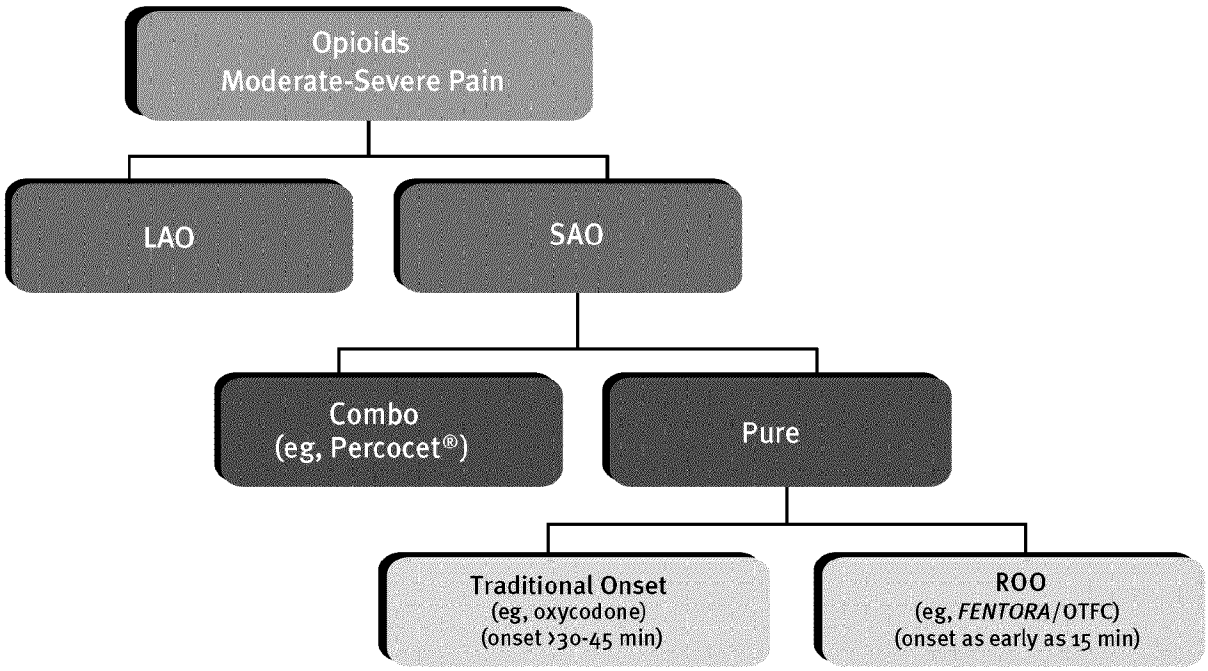
A study by Taylor et al of noncancer patients with chronic pain demonstrated that BTP can have a negative impact on patients' ability to work (93%) and finances (81%).[10]

Although the data are limited, it is clear that there are implications associated with suboptimal management of BTP. To help truly define and communicate the impact of BTP, more robust data are needed.

Situation Analysis

Treatment

Classification of opioids by type



There are numerous treatment alternatives for the management of chronic pain, including pharmacotherapy, rehabilitation techniques, alternative medicines, injections, infusions, and implantable devices. Pharmacologic options include nonsteroidal anti-inflammatory drugs (NSAIDs), acetaminophen (APAP), opioids, antidepressants, and anticonvulsants.[11]

For moderate to severe chronic pain, opioids are an important therapeutic option. The choice of opioid depends on the nature and severity of the pain, and patient tolerance or willingness to take the medication (perceptual concerns around addiction).

Classification of Opioids

The US opioid market consists of LAOs, SAOs (both pure and combination), and ROOs. The US Pharmacopeia (USP) classifies opioids by duration, as either LAO or SAO. SAOs are further categorized as combination or pure products.

Long-Acting Opioid (LAO)

LAOs are most commonly prescribed to treat the persistent component of chronic pain in patients. The duration of analgesia ranges from 8 to 72 hours, while onset of analgesia ranges from 45 minutes to 12 hours. Adjusting the dose and/or frequency of the LAO is often first-line treatment for BTP, even though the onset of analgesia does not match the early onset of pain during a BTP episode. While not considered a direct competitor, this treatment strategy results in ROO therapy being a third- or fourth-line option.

Short-Acting Opioid (SAO)

SAOs are sometimes used as first-line treatment for the persistent component of pain but are more commonly used as adjuncts to LAOs for BTP. Typically, prescribers will add or adjust the dose/dosage for the SAO for patients experiencing episodes of BTP. There are 2 classes of SAOs:

Combination SAOs (C-II and C-III) are the most frequently prescribed opioids. Examples of combination SAOs include Percocet and Vicoden®. Even though these products are often prescribed, they are less than ideal therapy for BTP because of limited dosing flexibility, maximum dose due to APAP, acetylsalicylic acid (ASA), and NSAID side effects, and the onset of meaningful analgesia can take up to 30 to 60 minutes. However, some physicians will prescribe combination SAOs for patients with BTP if they have a high comfort level and the experience and ease of prescribing these products.

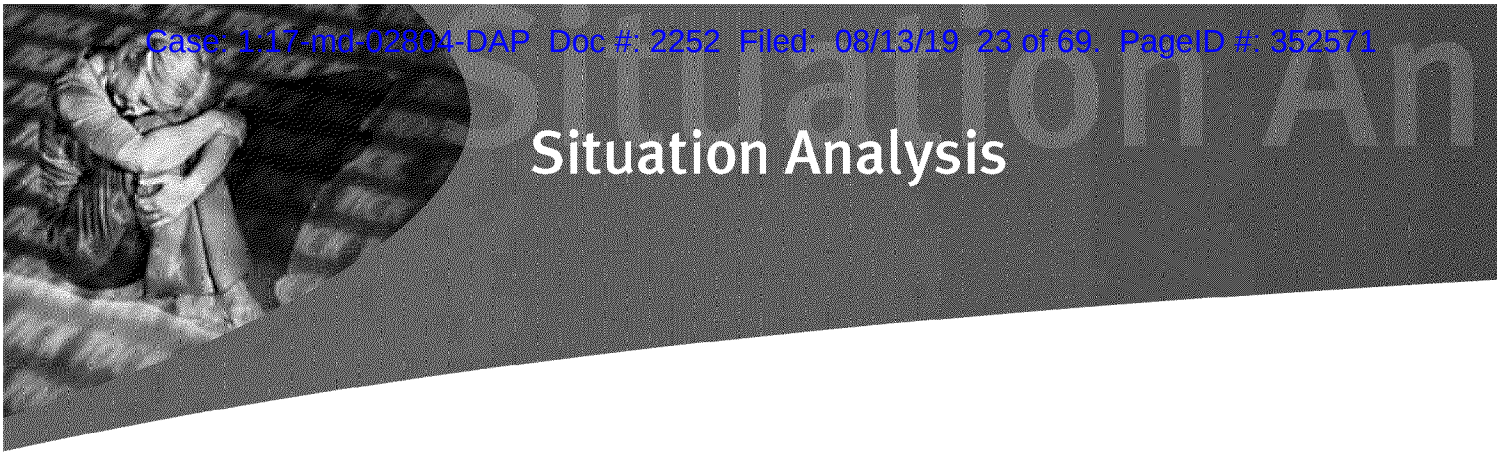
Traditional Pure SAOs (C-II) offer greater dosing flexibility than the combination SAOs and do not have APAP, ASA, and NSAID side effects. However, the onset of meaningful analgesia of 30 to 60 minutes and a 4- to 6-hour duration of action may not optimally match the characteristics of a typical BTP episode.

While not formally recognized by the USP, there is a push among some clinicians to further subcategorize pure SAOs based on their onset of pain relief. The "traditional" pure SAOs (oxycodone, morphine sulfate, hydromorphone) offer onset of action of 30 to 45 minutes.

Fentanyl-based buccal products (such as *FENTORA*, Actiq) have been shown to offer onset of action in 15 minutes or less. This group of products is termed ROO.

Rapid-Onset Opioid (ROO)

The ROO subclass consists of fentanyl-based products in unique mucosal delivery systems—the OTFC of Actiq, the OraVescent system of *FENTORA*, and the BioErodible MucoAdhesive (BEMA) technology of Onsolis (launched 10/09). Cephalon manufactures both the branded and generic OTFC ROOs and actively markets *FENTORA*.



Situation Analysis

Treatment Patterns

While the opportunity exists to increase the awareness and understanding among prescribers and patients about the recognition, communication, and treatment of BTP, there are HCPs that do have an understanding. These practitioners have employed numerous approaches to treatment.

By definition, patients with BTP manage the persistent component of chronic pain with around-the-clock (ATC) medications. Treatment regimens are individualized to manage the risk-benefit ratio. For patients in whom opioids are appropriate, ATC regimens include LAOs alone, SAOs alone, or a combination of an LAO plus an SAO.

Historically, the most common approach was to increase the dose or frequency of the LAO. The next common treatment choice was to adjust or add an SAO. Market research has found that the prescriber's perception of this approach to treat a BTP episode has shifted. The prescribers tend to add an SAO rather than increase the LAO for the treatment of BTP; switching to or adding a ROO is still the last course of action in the prescriber's mind.

The highlighted areas in the algorithm below show a discernable shift from 2007 to 2009 in the perceptions of prescriber's first-line approach for treatment of BTP.

Treatment Algorithm

Typical course of action[a] (aided)	LAO only	SAO only	LAO + SAO
Increase LAO dose/frequency (response from 2007 study)	28% (63%)[b]		45%
Increase SAO dose/frequency		33%	28%
Add/change LAO	5%	55%	8%
Add/change SAO (response from 2007 study)	61% (28%)[b]	9%	10%
Add *FENTORA* or OTFC	3%	1%	5%
Other	3%	2%	4%

[a] When patients report that the BTP treatment is inadequate and they are on either an LAO only, LAO and SAO, or SAO only, what would you typically do?
[b] Flores BTP Study 2007 (N=100).

While there may be an increased recognition of BTP, given the prescribers' perceived shift from LAO to SAO (61%) as the treatment choice for BTP, SAOs may not be the optimal treatment choice because they do not match the characteristics of a BTP episode, which is characterized as maximum intensity in as little as 3 minutes, striking without warning, and a median duration of 30 minutes per episode. Market research suggests that they are widely used due to nonclinical considerations such as cost and reimbursement, less perceived risk, ease of use, and familiarity.

Current Competitive Landscape

The current opioid market is saturated with generic drugs. Some of the branded products listed do compete for Share of Voice (SOV) within our targeted audience. The small- to mid-sized companies that market branded pain products are listed below.

Company	2008 US Pain Sales	Growth (+/-)	Key Pain Products Promoted	Sales Force Size	Products in Development
Purdue	$2.3B	+115%	OxyContin®[a] MS Contin® OxyIR® Ryzolt®	250	• Oxycontin CR • BTDS (transdermal buprenorphine)
King (Acquired Alpharma 12/08)	$1.1B	+20%	Avinza®[b] Kadian®[c] Skelaxin®[c] Flector® Patch[b] Embeda®[c]	Total: 669 Hosp: 100 Spec: 407 Pain: 157 Managed Care: 20	• Acurox • Remoxy abuse-resistant • Oxycodone NT abuse-resistant
Endo	$1.4B	+21.3%	Lidoderm®[b] Opana IR®[b] Opana ER®[b] Percocet®[c]	Total: 755 Pharma: 360 Specialty: 395	• Topical ketoprofen patch • Frova (new indication) • Axomadol
MEDA	$56MM	+65%	SOMA®[b] Onsolis™[c]	Total: 501 PCP: 426 Specialty: ~110	
ProStraken	Establishing US management team	N/A	No pain products Sancuso® (chemo-induced nausea and vomiting)	Building sales team of 67	• Abstral® (NDA submitted October 2009)
J&J	$465MM	+5%	Ultram ER®[b] Nucynta™[c] Nucynta ER™[c]	Total: 3,197 Pain: 550	

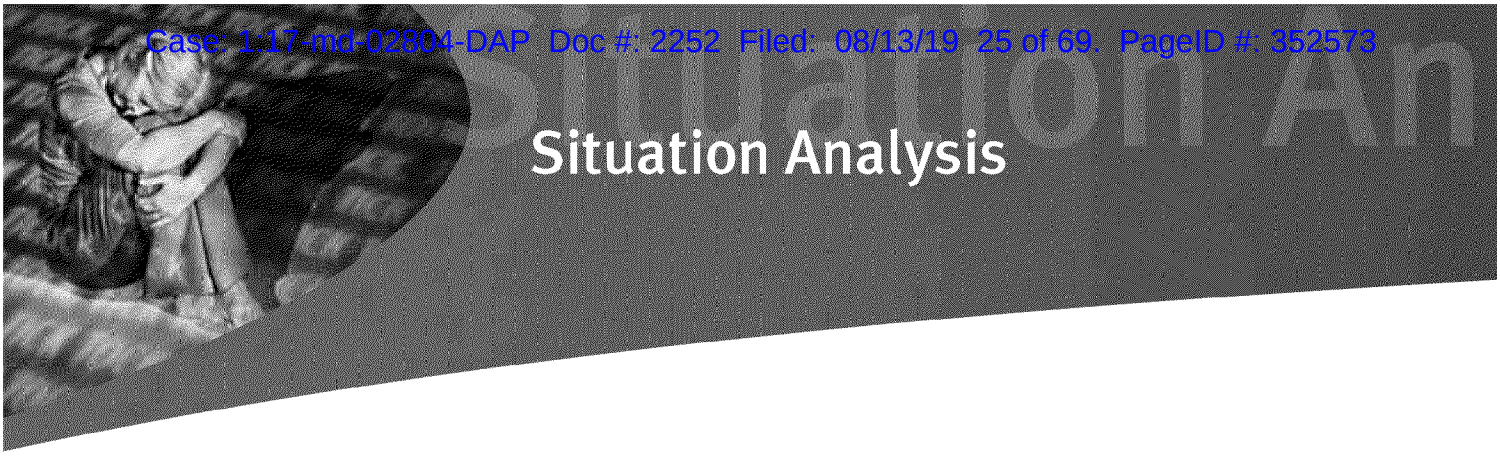
Source: IMS NSP; Dominion Group Competitive Intelligence Report Sept 2009; SDI, Sales Force Structures and Strategies 2Q 2009.

[a] Promotional Sales Force information not available for Purdue.

[b] Represents that the product was promoted during 2Q 2009.

[c] Represents that the product was not promoted during 2Q 2009.

LAOs are not considered direct competitors in the BTP market. SAOs used to treat BTP are considered direct competitors to *FENTORA*.

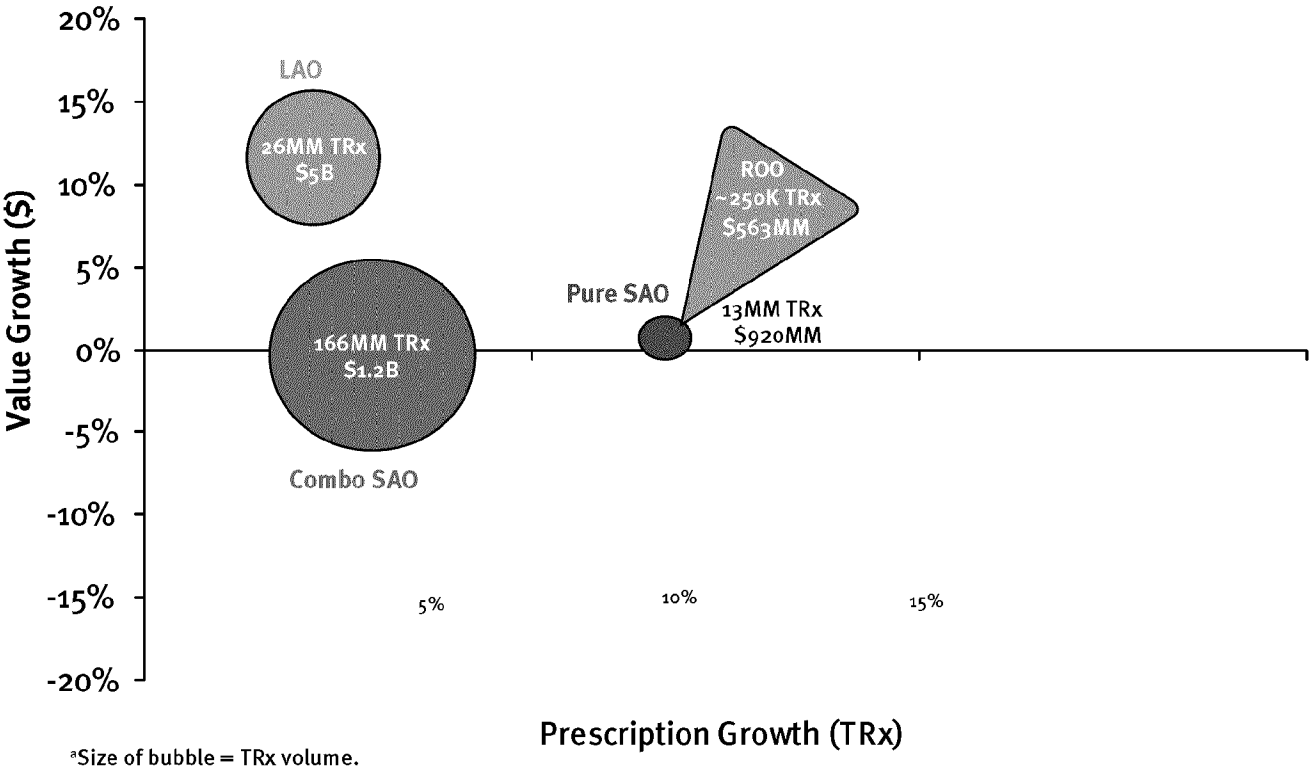


Situation Analysis

Opioid Market Performance

The US opioid pain market contains many low-cost generics and a relatively small number of promoted branded products. The majority of market volume is made up of generics, while the branded products represent most of the value. During the 12-month period ending June 2009, the total opioid market value was $7.2B, with growth of 11% and volume of 205MM TRxs with 5% growth. The LAOs (26MM TRx) experienced minimal growth (3%), with branded products driving 68% of the value. The pure SAO class (13MM TRx) had growth in volume (11%) but was relatively flat (1%) in value. The ROO subclass of the pure SAO declined in both value (-18%) and volume (-12%). Finally, combination SAOs (166MM TRx) showed continued growth in volume (5%) and value (5%).

Opioid Market Growth Rate[a] (Mat 6/08 vs 6/09)

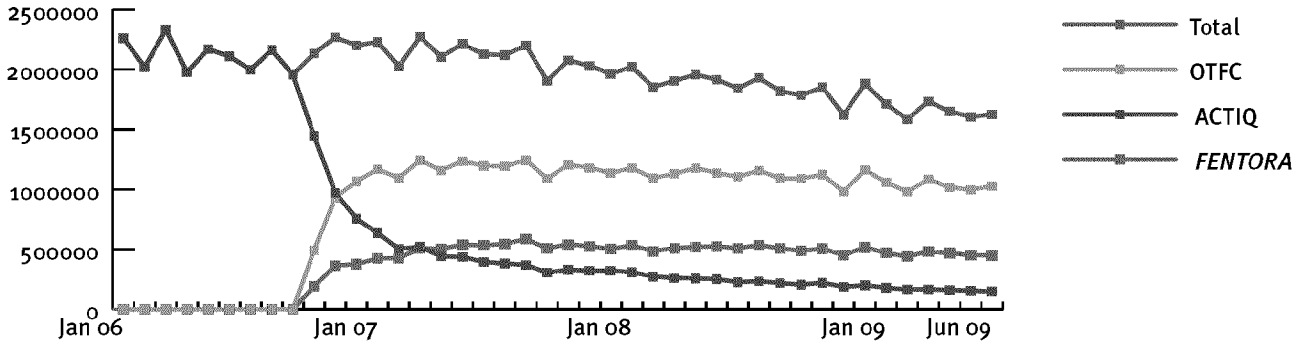


[a]Size of bubble = TRx volume.

Source: IMS NPA and NPS.

Secondary market research indicates that managed-care barriers to reimbursement such as prior authorizations (PAs) have increased for the ROO class. Market research also suggests that because of PA hurdles and extensive documentation, prescribers are less inclined to dedicate the time necessary to go through the reimbursement process for a ROO, and tend to choose simpler and more familiar alternatives like the low-cost generic SAOs. The result is a ROO volume decline of -12%.

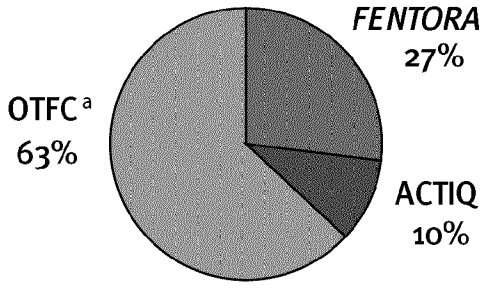
ROO Market Extended Unit Trends



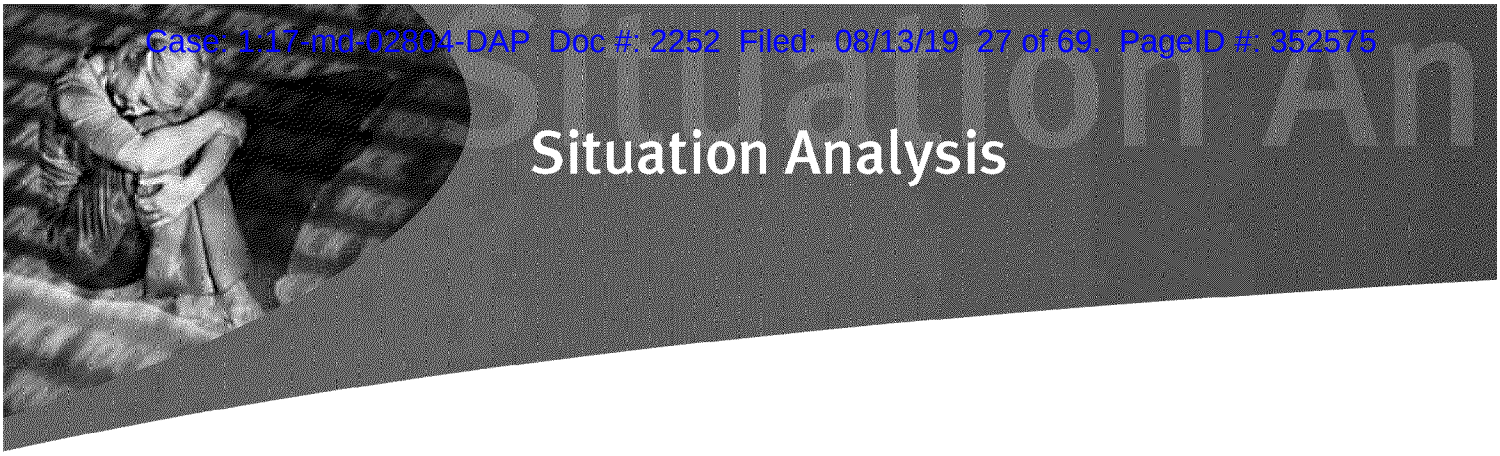
Source: IMS NPA.

Additionally, the value of the ROO market has declined. The ROO class was $563MM (MAT June 2009), representing an 18% decline compared to 2008. This can be attributed to 2 factors: (1) the subclass volume has shrunk, and (2) the price per unit has declined with the introduction of lower-priced generics.

ROO Market Volume
246 TRx



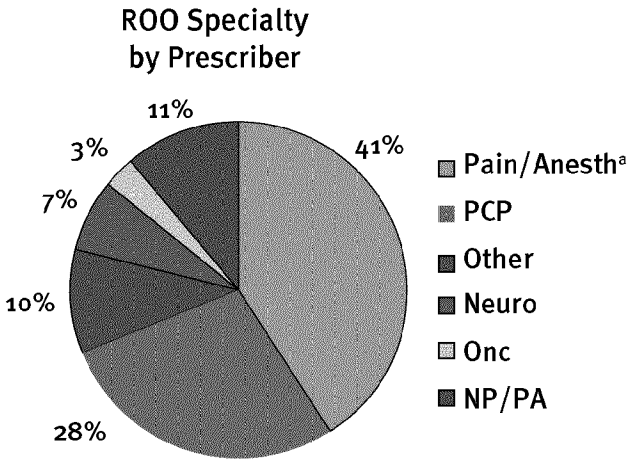
Source: IMS - NPA & NSP (MAT 6/09).
[a] Represents combined generic products.

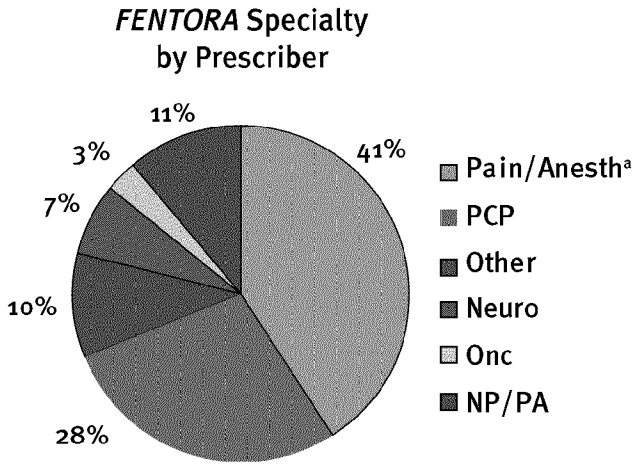


Situation Analysis

Prescribers

As demonstrated by the charts below, the majority of ROO prescriptions as well as *FENTORA* prescriptions are generated primarily by Pain/Anesthesiology/Physical Medicine & Rehabilitation, followed by PCPs. This distribution is consistent with both personal and nonpersonal targeting.





Source: IMS NPA (MAT 6/09).
[a] *Pain Medicine, Anesthesiology, Physical Medicine and Rehabilitation.*

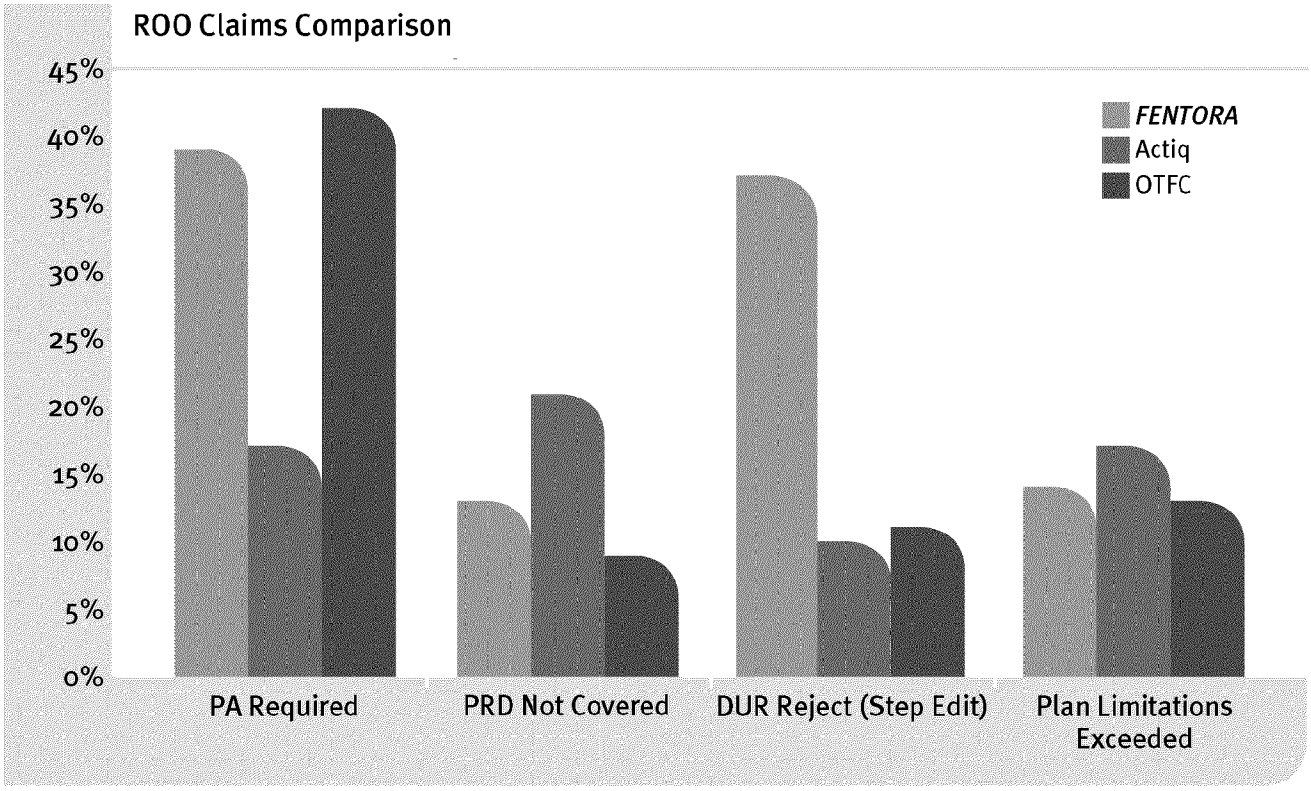
ROO Pricing[12]

ROOs are premium-priced products. Actiq is the most expensive ROO, with an average prescription cost of ~$5,300. A *FENTORA* prescription averages ~$2,500. Secondary data estimate that the cost of a generic OTFC prescription is ~$2,100. This estimate does not reflect the true cost of a generic prescription, as it does not reflect discounting, which may be as much as 50%.

Payer Landscape

The ROO payer landscape is primarily managed through third-party payers (82%). Due to the premium pricing of ROOs, managed care uses various tools to control pharmacy costs. Market trends suggest that ROOs are often subjected to prior authorization (PA), high copays, coinsurance, and quantity limits. These barriers can contribute to lower ROO utilization.

Generally, managed care applies the same restrictions on all ROOs. PA is a standard requirement, and copays are similar. When additional restrictions like step edits and quantity limits are in place, generics are treated the same as the branded products. (See tables below for comparisons.) Plans place the same restrictions on *FENTORA* prescriptions. While the majority of submitted *FENTORA* claims are eventually approved, it is not possible to determine the potential volume of prescriptions that were not written for *FENTORA* due to physician unwillingness to negotiate the reimbursement process.

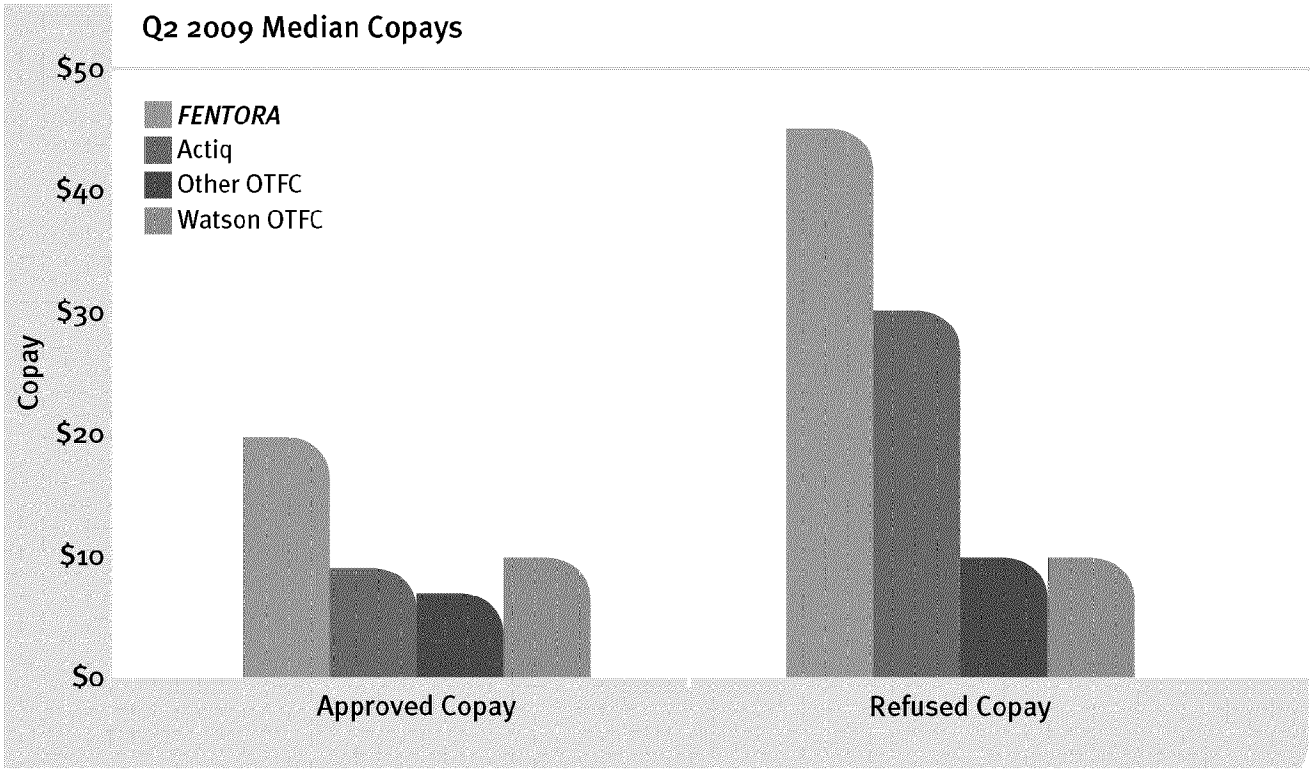


Source: WK.

Situation Analysis

Reimbursement issues also impact patients, specifically from a copay perspective. While ROOs may receive approval from the managed care plans, patients may still refuse at the point of dispensing, because of the high copay. In general, copays under $20 are acceptable to patients. However, we see increased refusal above $30. Approximately 3% of quarterly approved *FENTORA* claims are refused by patients.

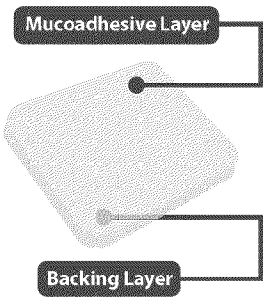
There is an opportunity to minimize patient refusals through appropriate reimbursement support programs.



Source: WK

Approved ROO Competitors in 2009

In 2010 and beyond there will be additional branded competitors that will enter the marketplace. Onsolis™ is the newest approved entry.



Onsolis

Onsolis, a branded ROO, was approved July 2009 and launched in October of 2009.

Product Profile

Name	Onsolis
Company	Technology: developed by BioDelivery Sciences International, Inc (BDSI) Commercial: MEDA/ MedPointe AB.
Product forecast	$200MM peak year sales
Other pain products	SOMA
Status	Approved July 2009 (launched Q4 2009)
Indication	The management of BTP in patients with cancer, 18 years of age or older, who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain
Description	Uses the BioErodible MucoAdhesive (BEMA™) bilayer delivery technology which is comprised of water-soluble polymeric films
Administration	A buccal-soluble disc designed to adhere to oral mucosa in less than 5 seconds and completely dissolve within 15-30 minutes
Dosage strengths	200-, 400-, 600-, 800-, 1200-mcg
Distribution	Specialty pharmacy

Source: BDSI investor report. September 29, 2009.

Pharmacokinetics

Parameter	Onsolis, mean[a]
C_{max} (ng/mL)	1.67
T_{max} (min)	60
T_{first} (min)	9
AUC_{inf} (hr*ng/mL)	11.4-14.5
Bioavailability	70%[b]

[a] Data presented at ASA, Orlando, FL, October 2008.
[b] Vasisht et al. APS Poster. Dose linearity and absolute bioavailability of BEMA fentanyl in healthy volunteers. May 8, 2008.

Situation Analysis

Efficacy

According to data presented at the American Society of Anesthesiologists in October 2008, Onsolis demonstrated:

- Improvement in Sum of Pain Intensity Differences (SPID) at 15 minutes, sustained to 60 minutes
- Improvement in the following secondary endpoints
  - Pain intensity
  - Pain relief
  - Use of rescue medication
  - Patient satisfaction with treatment

Customer Perceptions

Primary research conducted in April 2009 indicated that prescribers generally viewed Onsolis and *FENTORA* as parity products and did not perceive any meaningful clinical difference. The differences noted were related to the delivery system and different dosage strengths (lack of 100 mcg and the availability of 1200 mcg).

Onsolis was approved with a REMS that utilizes a specialty pharmacy distribution system. Customer feedback stated concerns that this system could increase the potential for diversion, hamper patient access to therapy, and would place additional burdens on prescribers and office staff.

MEDA Market Conditioning

MEDA market conditioning activities have included dissemination of clinical data at major pain meetings, issuing press releases, and holding webcasts. Based on these activities, it is anticipated that MEDA will place significant promotional muscle behind Onsolis. Additionally, Onsolis has been approved with a REMS, known as FOCUS™ (Full Ongoing Commitment to User Safety). With this program, Onsolis will only be available through specialty pharmacies.

The table below is a comparison of *FENTORA* and Onsolis. The highlighted boxes indicate the key attributes or strengths that MEDA is expected to leverage upon launch.

Attribute Comparison

Key Attributes	Buccal Tablet	Onsolis Buccal Film
Indication	BTP in CA pts (99-14) (pursuing BTP in non-CA patients)	BTP in CA pts (pursuing BTP in non-CA patients; clinical program to be initiated in Q1 2010)
Onset	15 min	15 min
Duration	60 min	60 min
Absolute bioavailability	65%	70%
Dosage	100-800 mcg	200-1200 mcg
Safety	Comparable	Comparable
Mucosal irritation	Low	Minimal/none
Taste	"Baking soda"	Mint
Clinical data	Breadth of clinical database and publications	Limited clinical database, only abstracts and posters
Sales force size	110 PCS 2 product calls	~100 specialty primary position expected
Targets	~6000	High ROO prescribers

Sources: BioDelivery Science International, April 25, 2007; Press release: Onsolis™ Fentanyl Demonstrates Substantial Transmucosal Delivery in Absolute Bioavailability Study; Press release: May 14, 2007 BDSI Announces Positive Key Secondary Endpoint Results for Onsolis™ Fentanyl; Press release: December 17, 2007; BioDelivery Science International November 19, 2008; Press release: BioDelivery Science Remains on Schedule for December Onsolis Resubmission Following Meeting with FDA; Webcast: November 7, 2008: BioDelivery Sciences to Meet with FDA to Finalize Proposed REMS for Onsolis. *FENTORA* PI, October 2007; Onsolis PI, July 2009.

Commercial Strategies

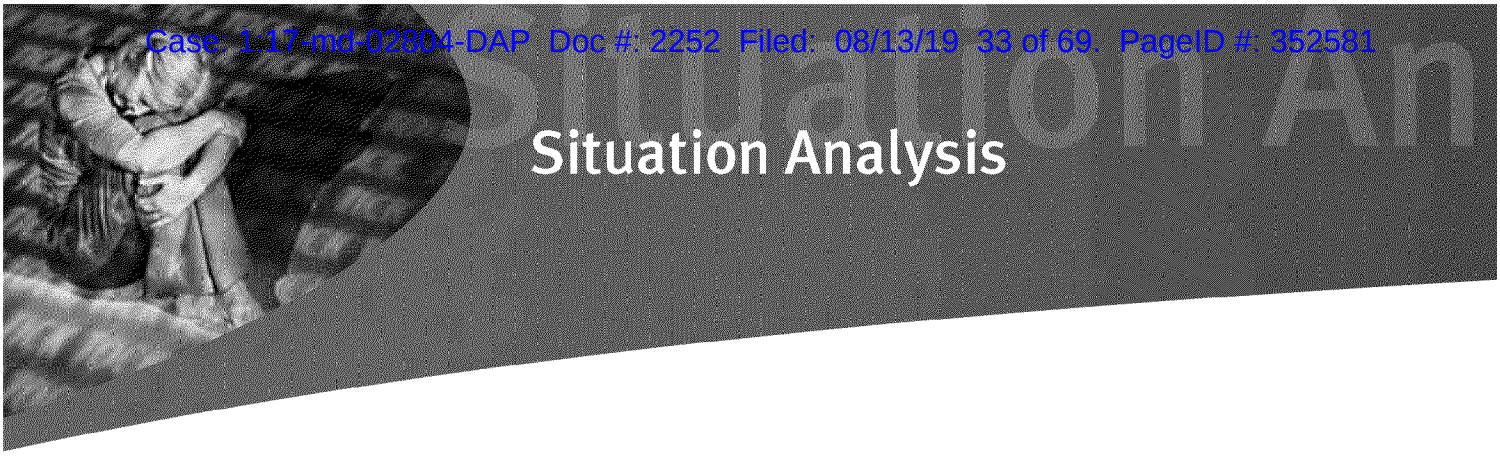
The MEDA sales force is similar in number to the size of the *FENTORA* field force (~110) and will target current ROO prescribers and oncologists. MEDA will need to focus on establishing Onsolis attributes as well as educating HCPs on the details around FOCUS, their REMS program.

What is unknown is the overall commercial investment regarding share of voice (ie, nonpersonal promotion). CI monitoring suggests MEDA will focus on a simple message—"adheres, dissolves, delivers"—while messaging against *FENTORA* on the following points:

- Broad range of doses up to 1200 mcg dosage strength
- Well tolerated in oral cavity
- Unique technology (BEMA™)

Additionally, as stated above, there will need to be significant education on the REMS process, as well as ongoing support efforts, as FOCUS is the first ROO REMS to be approved and is a new protocol for key stakeholders to follow.

The pricing strategy of Onsolis is at parity with *FENTORA*. Should MEDA employ an aggressive contracting/pricing strategy, it could negatively impact *FENTORA* business.



Mallinckrodt/Covidien: Oral Transmucosal Fentanyl Citrate (OTFC)

OTFC is the third approved (10/09) ROO that will enter the market and is expected to launch in early 2010. The launch will be accompanied by an extensive risk management plan. The introduction of this third generic is expected to increase the pressure on pricing and reimbursement of branded ROOs.

Near-term ROO Competitors

Abstral

Abstral is a sublingual formulation of fentanyl. The NDA was submitted and accepted for review in October 2009. Subject to successful completion of the US approval process, ProStrakan plans to launch Abstral in the USA in the second half of 2010.

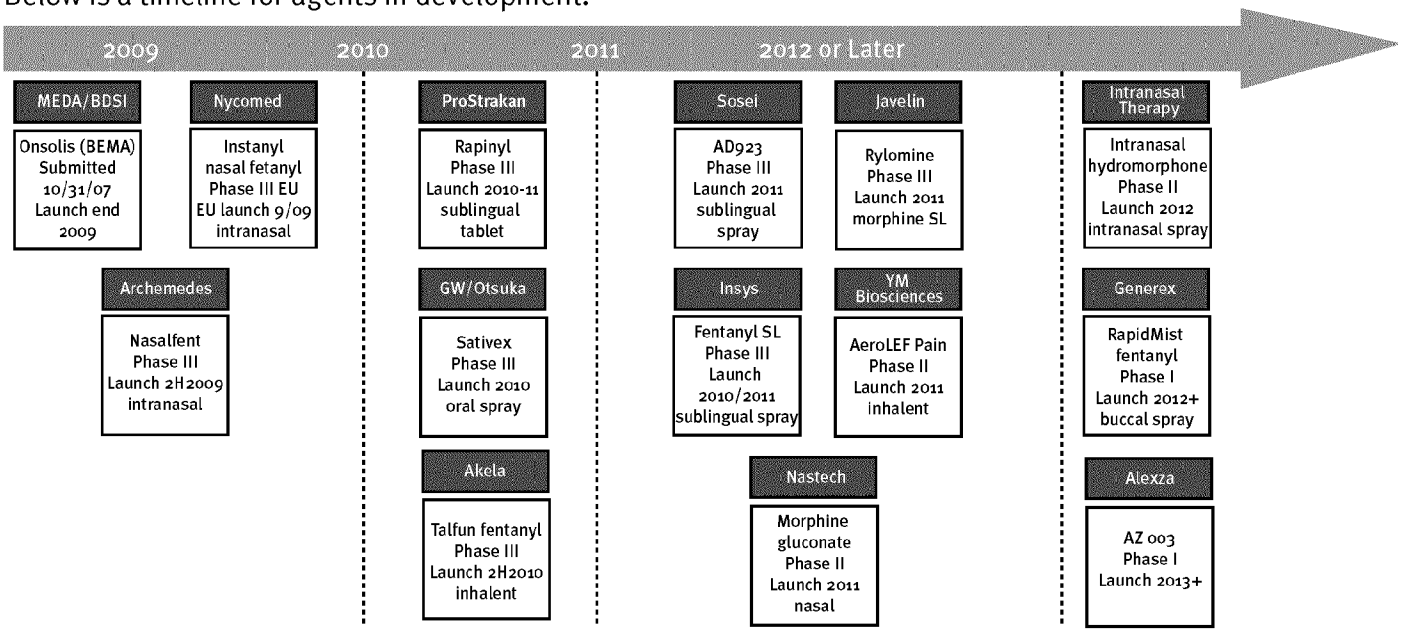
Sandoz: Generic OTFC

Competitive intelligence (CI) monitoring indicates that Sandoz has filed for approval of OTFC. The entry of this generic is contingent upon the approval of the ROO REMS. No additional details are available at this time, but CI will continue to monitor this potential competitor.

Product Development in 2010 and Beyond

In the BTP segment, a host of opioid products are in development. The products in development may see weakness in the available products, specifically in the mode of delivery or current technology. Future agents are centered on sprays and inhaled products, which may have a faster onset than current oral mucosal products.

Below is a timeline for agents in development.



Additional Influencers: REMS

Abuse, Addiction, and Diversion [13]

Chronic pain is commonly undertreated and is a widespread problem. One barrier to successful management of chronic pain with opioids is the concern associated with abuse, addiction, and diversion. These concerns are shared by patients, physicians, pharmacists, law enforcement, drug regulators, and policy makers. Despite the mounting evidence that demonstrates an effective analgesia improves quality of life, barriers do persist. National pain organizations, law enforcement, and regulators continue to evolve strategies to ensure opioids are available for appropriate patients while minimizing the associated risks.

In an effort to manage risks associated with use of opioids, the FDA requires select medications to have REMS. REMS programs are designed to meet specific goals and objectives in minimizing risks while preserving benefits.

Risk Minimization Programs

While the benefits of opioids are well established in the treatment of pain when used appropriately, there is a growing concern over prescription opioids when they are misused or abused. Because of the issues of misuse, abuse, diversion, and in some cases death, opioid agents are perceived by some as a major public health crisis.

The FDA believes that the current risk minimization strategies for intervening are inadequate. Because of the authorities under the Food and Drug Administration Amendments Act (FDAAA) of 2007, risk minimization programs must meet specific criteria, provide efficacy measurements, and include corrective actions. If companies fail to meet the risk minimization requirements, they would be subject to severe penalties.

Evolution of Risk Management

Risk minimization plans have been utilized for opioids for a number of years. Since their inception, there have been a number of modifications and requirements that have been incorporated. Originally, these programs were known as Risk Management Plans (RMP). These early plans were an iterative process of assessing a product's benefits-risk balance, developing tools to minimize any risk, and evaluating the effectiveness of those tools. The program evolved from an RMP to a Risk Minimization Action Plan (RiskMAP), which was a strategic safety program designed to meet specific goals and objectives. Today these programs are referred to as REMS.

Situation Analysis

REMS, the newest iteration of risk management programs, are mandated by the FDA to assure safe use of a product and to ensure that the benefits of the drug or biological product outweigh the risks of the product. There are a number of FDA-identified elements that are intended to assure safe use. These are listed in the table below:

Elements to assure safe use[a]
1. Prescribing restricted to HCPs who have particular training or experience, or who are specially certified
2. Special certification of pharmacies, practitioners, or healthcare settings that dispense the drug
3. Dispensing of the drug restricted to certain healthcare settings (eg, hospitals)
4. Dispensing of the drug restricted to patients who have evidence of safe-use conditions (eg, laboratory test results)
5. Mandatory monitoring by HCPs of all patients using the drug
6. Requirement for all patients using the drug to be enrolled in a registry

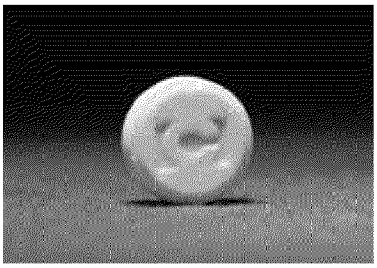
Source: FDAAA Title IX 2007– drug safety.
[a] All elements may not be required for all products.

While there is widespread resistance to a class-wide opioid REMS, these programs are forthcoming. In 2010, the ROO class will experience the initial impact of these programs, as this subclass is on a more aggressive regulatory clock than either of the LAOs or SAOs. These agents will most likely have similar REMS programs implemented sometime in 2011. Due to the difference in program timing, the ROO class may experience a "balloon squeeze" effect. This effect refers to the potential for prescribers to choose an agent without a REMS program, driving the prescriber, for example, to SAOs for the treatment of BTP that do not currently have restrictive REMS.

Product

Description

FENTORA (fentanyl buccal tablet) is an innovative therapy developed to optimize fentanyl absorption using the unique OraVescent® technology. *FENTORA* provides early onset of pain relief[a] and duration of 60 minutes[b] that match the characteristics of a BTP episode. *FENTORA* is also a discreet buccal tablet that is sugar free.



FENTORA C-II is a potent opioid analgesic intended for buccal mucosal administration. *FENTORA* is formulated as a white, flat-faced, round, beveled-edge tablet.

FENTORA is designed to be placed and retained within the buccal cavity for a period sufficient to allow disintegration of the tablet and the absorption of fentanyl across the buccal mucosa.

FENTORA employs OraVescent drug delivery technology that generates a reaction that releases carbon dioxide when the tablet comes in contact with saliva. It is thought that transient pH changes accompanying the reaction may optimize dissolution (at a lower pH) and membrane permeation (at a higher pH) of fentanyl across the buccal mucosa.

FENTORA is packed in cartons that contain 7 blister cards with 4 tablets in each card. Tablets are encased in child-resistant foil and available in the following dosage strengths:

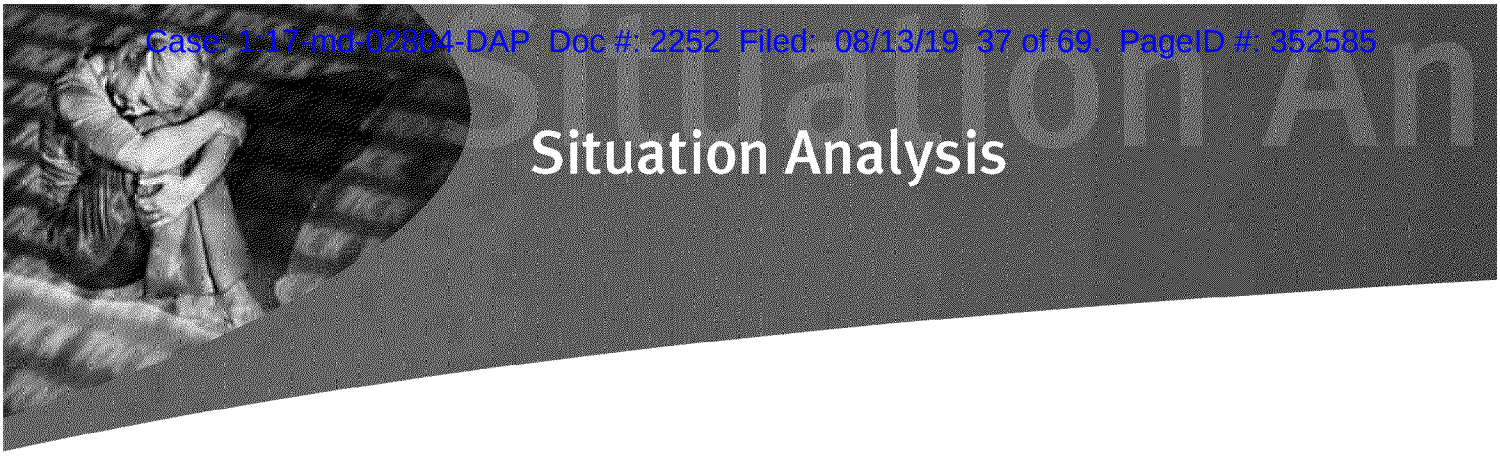
Dosage Strength (fentanyl base)	Debossing	Carton/Blister Package Color
100 mcg	1	Blue
200 mcg	2	Orange
400 mcg	4	Sage green
600 mcg	6	Magenta (pink)
800 mcg	8	Yellow

Note: the 300-mcg dose was discontinued in Q2 2009 due to low utilization.

Indication

***FENTORA* is indicated only for the management of breakthrough pain in patients with cancer who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.**

[a] 15 minutes (first time point measured).
[b] 60 minutes (last time point measured).



Clinical Profile

Pharmacokinetics

Four pharmacokinetic studies were conducted to characterize *FENTORA*. See tables below.

NDA Cancer Label

1026	Bioequivalence 4x100 ff 1x400
1027	Dose proportionality
1028	Absolute & relative bioavailability
1029	Multiple kinetics

Pharmacokinetic Profile

Parameter	*FENTORA*
C_{max} (ng/mL)	Mean 1.65
T_{max} (min)	Mean 46.8
$AUC_{0\text{-}inf}$ (hr*ng/mL)	Mean 30.9
Buccal absorption	48%
GI absorption	17%
Absolute bioavailability	65%

Efficacy

Clinical safety and efficacy in opioid tolerant patients with cancer was demonstrated in 2 trials. These efficacy data help to differentiate the onset and duration of *FENTORA* from those of SAOs.

Efficacy/safety	Result
Primary endpoint	SPID30 achieved
Onset (PID & PR)	15 min
Duration (PID & PR)	60 min
Most common AEs observed (>10%)	Nausea, dizziness, headache, fatigue, vomiting, somnolence
GI absorption	17%
Absolute bioavailability	65%

Positioning/Messaging

Positioning Statement

FENTORA is the first and only buccal tablet that utilizes an OraVescent® reaction to provide early onset of analgesia, matching the characteristics of BTP.

Reason to Believe

FENTORA employs OraVescent® drug delivery technology that generates a reaction that releases carbon dioxide when the tablet comes in contact with saliva. It is thought that transient pH changes accompanying this reaction may optimize dissolution (at a lower pH) and membrane permeation (at a higher pH).

Key Messages

Current messaging communicates product features, appropriate patient selection, and safe and proper use of *FENTORA* in opioid tolerant patients with cancer.

Product Messages
Core message: *FENTORA* provides early and sustained relief of BTP for appropriate opioid tolerant patients
• Supporting points: —Efficacy —Onset of pain relief within 15 minutes in some patients —Duration of pain relief through 60 minutes —Clinically significant decrease in pain intensity at all time points
• Unique delivery system —OraVescent drug delivery technology may optimize delivery of fentanyl across the buccal mucosa —Fentanyl is readily absorbed, achieving an absolute bioavailability of 65% —Convenient, discreet, and sugar-free tablet
• Safety —Common side effects: comparable to other opioids, except for application site abnormalities (8%) —Serious side effects: life-threatening respiratory depression could occur at any dose in opioid non-tolerant

Situation Analysis

Safety Messages
Selecting appropriate patients
• Establish that the patient has BTP
• *FENTORA* contraindicated in the management of acute pain or postoperative pain, including headache/migraine
• Ensure the patient is opioid tolerant during treatment with *FENTORA* —Patients must be on >60 mg of oral morphine or an equianalgesic dose of another opioid daily for a week or longer
Proper dosing with *FENTORA*
• Initiation: starting dose = 100 mcg — *FENTORA* is not a generic version of any other transmucosal fentanyl product and cannot be substituted for any other fentanyl product. Do not convert patients on a mcg-per-mcg basis
• Titration: from the starting dose, titrate to a dosage strength that provides adequate analgesia with tolerable side effects
• Maintenance: once a successful dose is established, maintain using a single tablet

Any reference to BTP in context of strategy/promotion refers to BTP in opioid tolerant patients with cancer until an approved change in indication.

In 2010, the *FENTORA* messaging will be reevaluated to ensure that it is concise and resonates with the target audience. Messaging will continue to focus on product strengths of *FENTORA* for the treatment of BTP in patients with cancer. Key messaging will evolve to emphasize the onset and duration of effect in relation to a typical BTP episode and the potential for positive outcomes in appropriate opioid tolerant patients with cancer and BTP.

Customer Perceptions

In the July 2009 ATU Study of *FENTORA* targets, the total awareness of *FENTORA* (aided and unaided) among current[a] writers and non-writers was 79%, with unaided awareness at only 29%. It is a generally accepted industry standard that a high top-of-mind awareness (~80%) drives product utilization. Conversely, the SAOs have a high awareness.

FENTORA ATU Study: July 2009

Parameter	*FENTORA*	Leading SAOs
Unaided awareness	29%	59%-65%
Total awareness (unaided and aided)	79%	93%-97%
Ever prescribed	40%	88%-93%
Prescribed in the past month	23%	61%-87%
Intent to maintain or increase prescribing	91%	93%
Satisfaction score (writers)	5.4 out of 7	4.8 out of 7
Likelihood to recommend	4.8 out of 7	NA
Ranking[b]: early onset of action	1st	4th
Ranking: sufficient clinical data	2nd	1st
Ranking: ease/convenience of delivery system	1st	2nd
Ranking: improves patient quality of life	1st	4th

Source: *FENTORA* ATU Study: July 2009.
[a] Defined as writers who have prescribed *FENTORA* in the last 6 months.
[b] 1 being low and 7 being high.

Situation Analysis

Customers state that the product attributes of early onset, effective pain relief, short duration of effect, and improved patient QOL are important in the treatment of BTP. This would suggest the likely choice of a ROO such as *FENTORA*. However, these attributes do not drive prescriber choice, nonclinical considerations do.

FENTORA Compared to Other BTP Options

More Important

Less Important

Decision Criteria	ACTIQ	Generic OTFC	All Other SAOs
Efficacy of pain relief	=	+	+
Efficacy in treating severe pain	=	=	+
Patient's quality of life	=	=	+
Out-of-pocket affordability to patient	=	-	-
Onset of action (how soon patients experience meaningful relief)	=	+	+
Insurance plan coverage	=	-	-
Ease and convenience of medication delivery system	=	=	=
Managed Care Organization approval	=	=	-
Incidence of opioid side effects	=	=	+
Availability at local pharmacies	=	=	-
Dosing instructions	=	=	=
Prescribing restricted by indication	=	=	-
Uniqueness of medication delivery system	=	+	+

Source: GfK Healthcare – *FENTORA* ATU, 6/9 (N=150).

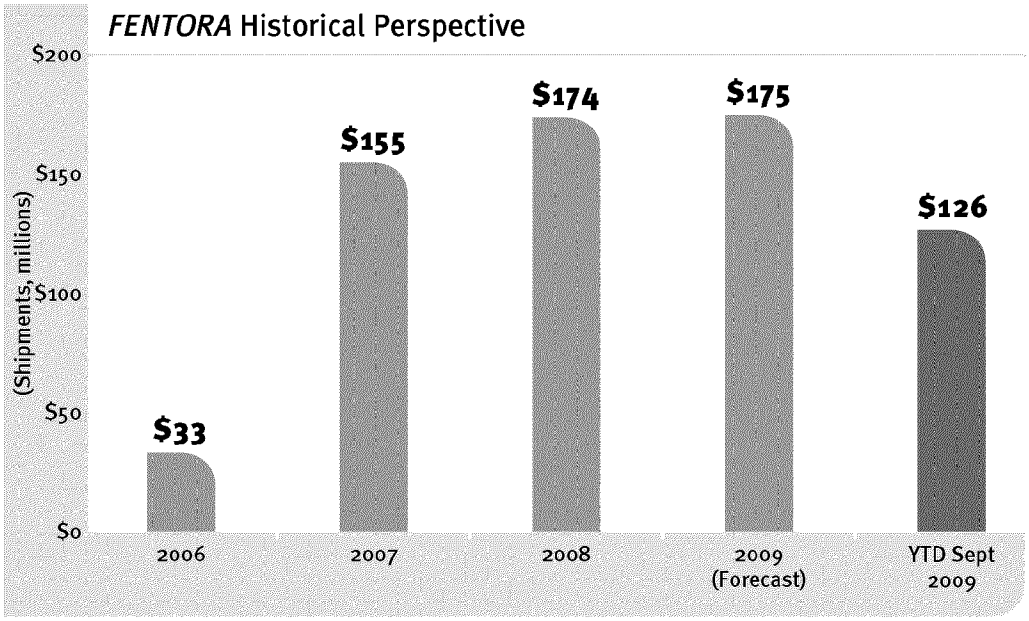
= Equal
+ *FENTORA* is better
- Competitor is better

Not only are SAOs top-of-mind, but prescribers also perceive both *FENTORA* and SAOs as satisfactory treatment options for BTP. In 2010, prescriber awareness must increase as well as the meaningful value they believe *FENTORA* provides over SAOs for the treatment of BTP in order to rebuild the foundation for long-term *FENTORA* growth.

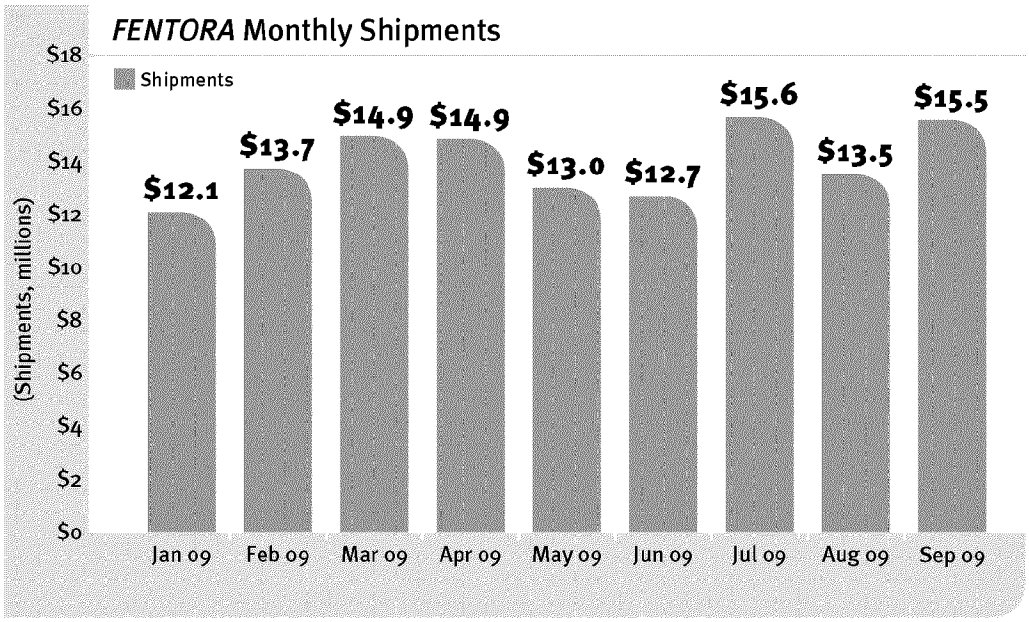
FENTORA Performance

Value and Volume

Shipments



Source: Internal Shipment Data.

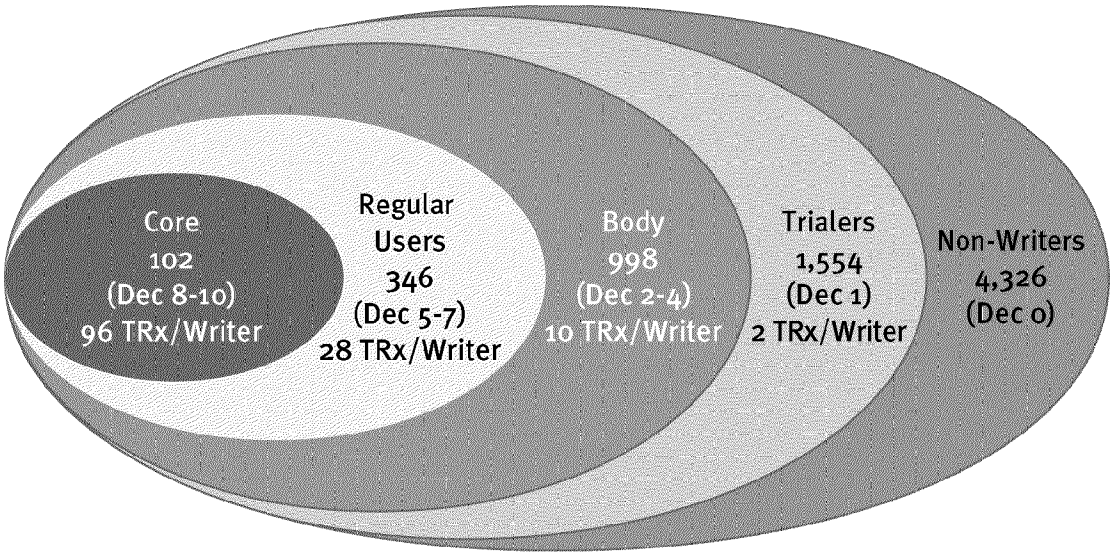


Source: IMS NGPS.

Situation Analysis

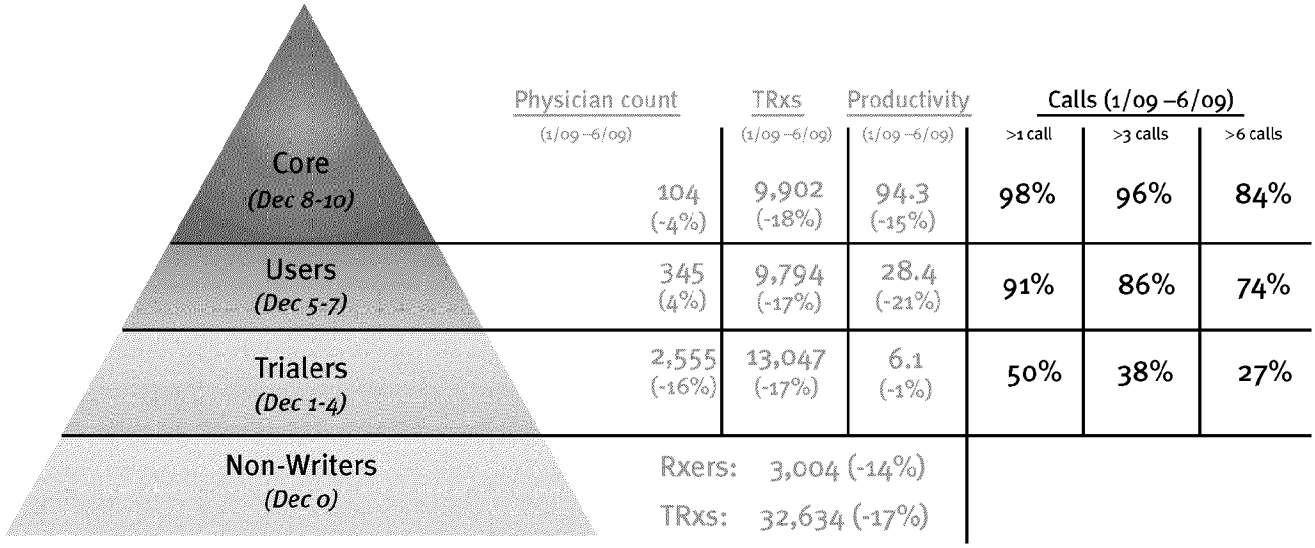
FENTORA Target Analysis

The universe for *FENTORA* is made up of a small number of high prescribers. The representatives focus on deciles 2-10 (~1500) and marketing efforts are focused on the entire ~7300.



Source: Internal Shipment Data.

The activity of the representatives on those higher decile prescribers is reflected below.

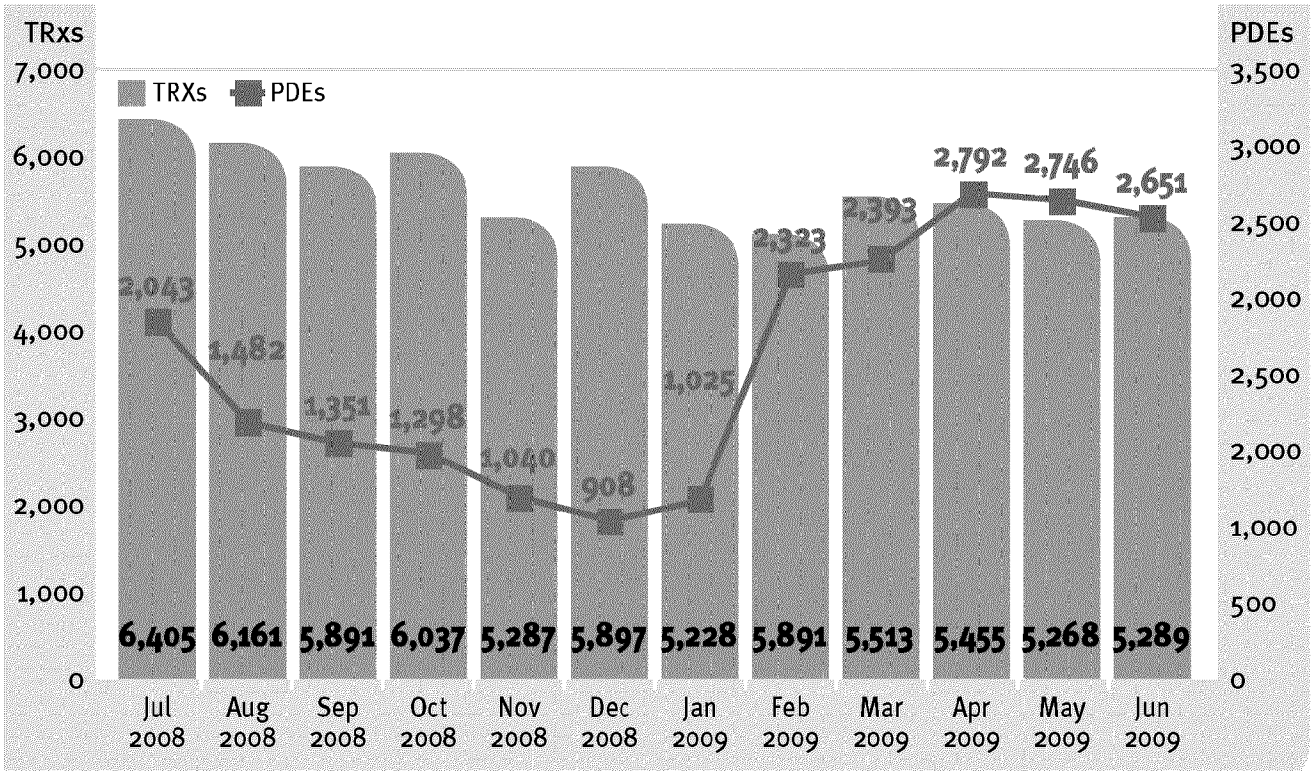


	Physician count (1/09–6/09)	TRxs (1/09–6/09)	Productivity (1/09–6/09)	Calls (1/09–6/09) >1 call	>3 calls	>6 calls
Core (Dec 8-10)	104 (-4%)	9,902 (-18%)	94.3 (-15%)	98%	96%	84%
Users (Dec 5-7)	345 (4%)	9,794 (-17%)	28.4 (-21%)	91%	86%	74%
Trialers (Dec 1-4)	2,555 (-16%)	13,047 (-17%)	6.1 (-1%)	50%	38%	27%
Non-Writers (Dec 0)	Rxers: 3,004 (-14%)	TRxs: 32,634 (-17%)				

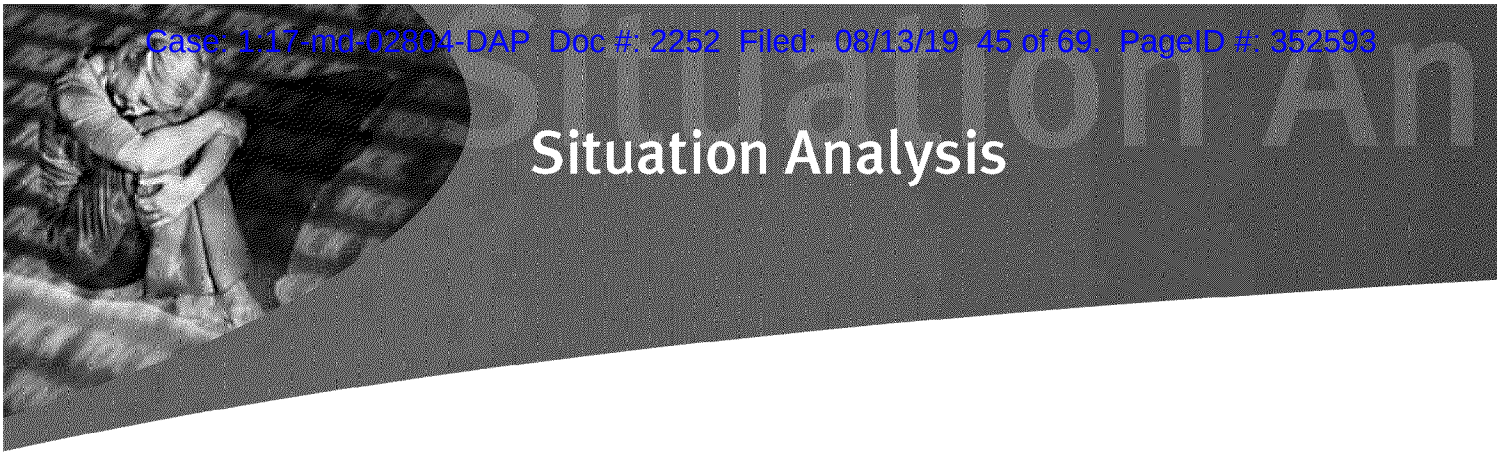
Source: WK Source Prescriber, Jan 08 – June 2009, Sales Operations.

Sales Force

Sixty representatives were added in February 2009 to the Pain Care Sales Force. The increase resulted in an upswing of PDEs but did not translate into an increase in prescriptions, as was expected since 2009 was a maintenance year for *FENTORA*. Redaction - Other Teva Product AMRIX, Redaction - Other Teva Product AMRIX Redaction - Other Teva Product Redaction - Other Teva Product. In order to maximize ROI, the sales force targeted the most productive *FENTORA* prescribers (deciles 2-10).



In 2010, the targeted reach and frequency will be reevaluated to ensure that the appropriate productive prescribers are being targeted and detailed on *FENTORA* in order to establish and reinforce its position as preferred treatment of BTP in opioid tolerant patients with cancer. Messages will continue to provide important safety and dosing information in an effective manner that resonates with our prescribers.

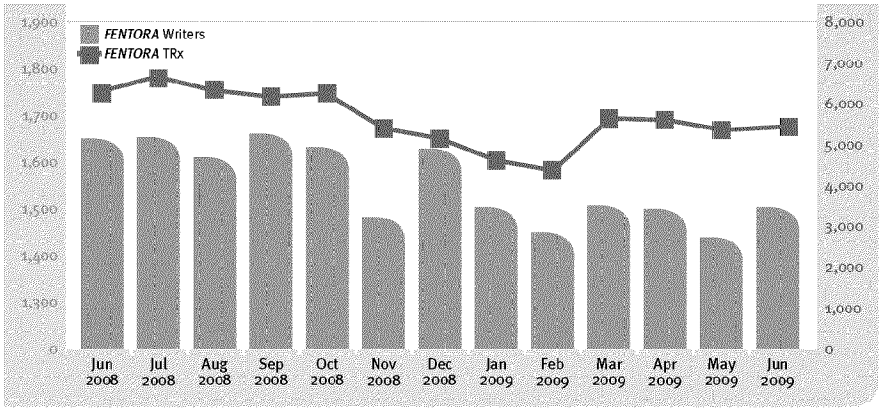


Prescriber

Pain specialists write the majority (48%) of *FENTORA* prescriptions, followed by PCPs (21%). Oncologists write 3% of *FENTORA* prescriptions. Overall, there has been a decline in the number of pain specialists prescribing *FENTORA* on a monthly basis, as demonstrated in the graph below.

Additionally, there has been a drop in physician productivity across all specialties. Productivity is defined as the calculated number of prescriptions written by a physician in a month.

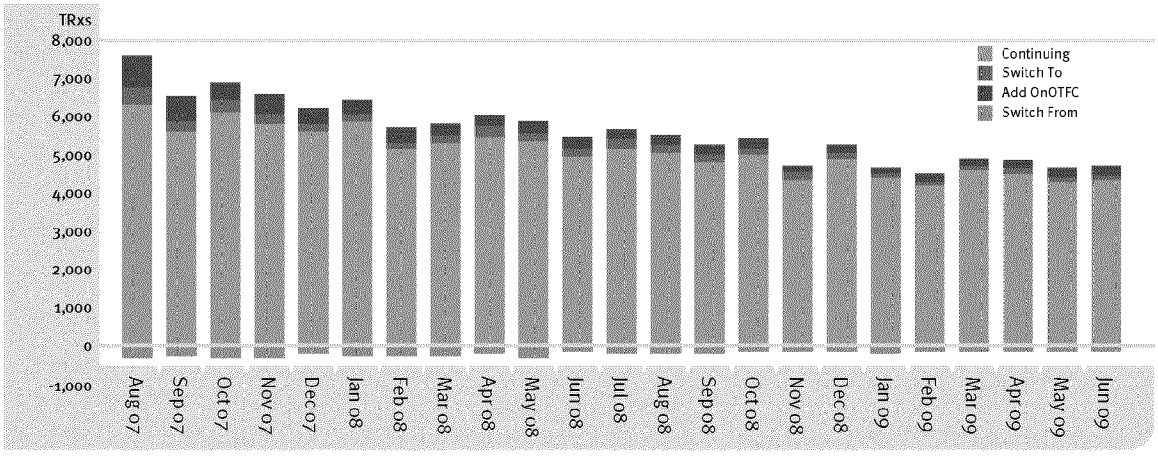
The 2 main reasons for the drop in productivity are a decrease in personal promotion (30% weighted) and an increase in managed care hurdles. In 2010, if promotional resources are reallocated with a greater weighting toward *FENTORA*, effective promotional efforts may observe an increase in prescriber productivity.



Source: WK Source Prescriber.

Source of Business

Continuing therapy makes up the majority of *FENTORA* prescriptions at 90%. Add-on therapy and switches constitute 5% and 4%, respectively, with only 2% of the overall business coming from new starts.[12]

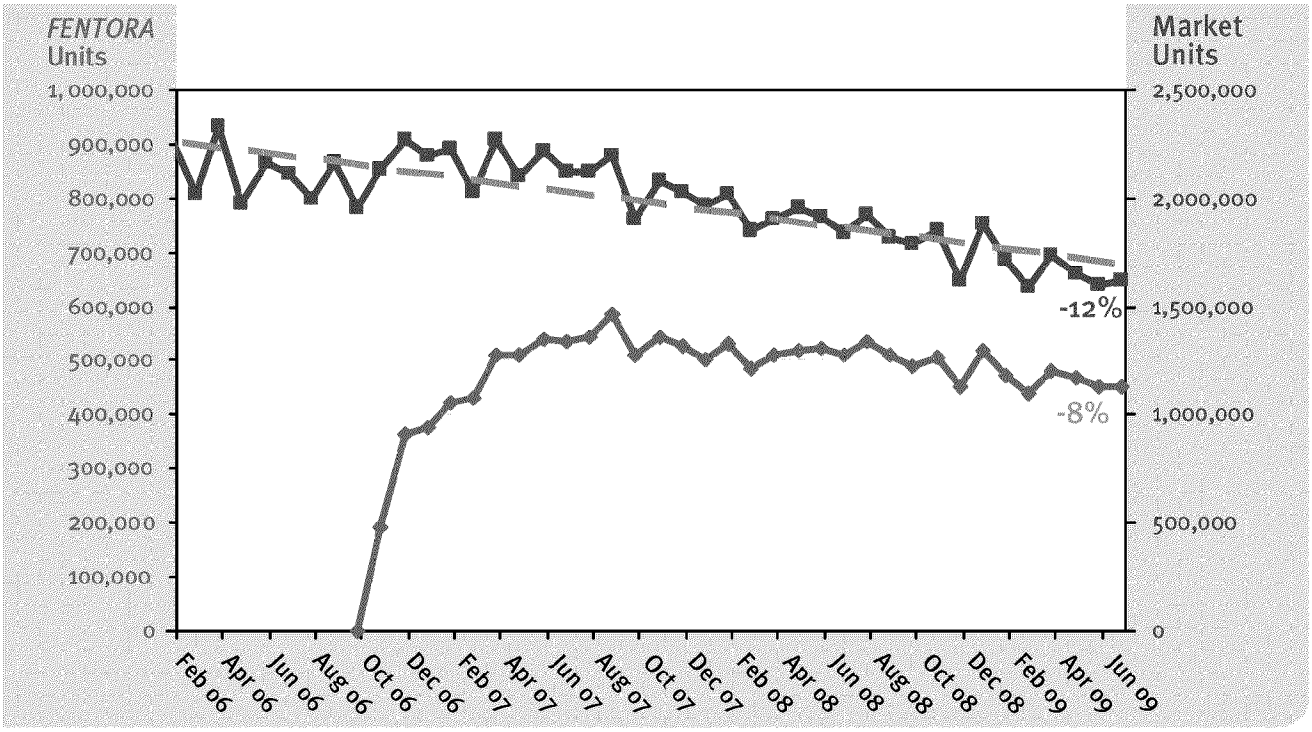


Source: IMS NPA/Sales Ops internal data.

FENTORA Performance

Overall, with only 30% of sales force resources, a declining and less productive prescriber base, and very few new *FENTORA* starts for appropriate patients, *FENTORA* has experienced a decline of 8% in 2009. When this is compared to the ROO market at -12%, it would suggest that even limited personal promotion has a positive effect, as a 28% share of the market has been maintained. In order for *FENTORA* to be successful in 2010, we need to solidify its position in a changing marketplace.

FENTORA and ROO Market Units (Mat 6/08 vs 6/09)



FENTORA must establish itself as the market leader in product attributes, marketplace knowledge and experience, and leverage its innovative approach to the REMS imperatives.

Situation Analysis

SWOT Analysis

Strengths

- Highly efficacious
- Onset of 15 minutes
- Multiple and convenient routes of administration[a]
- Recently completed clinical studies (head-to-head)
- Patent to 2019

Weaknesses

- Patient safety ramifications in non-opioid tolerant patients
- Cost > value perception
- Physician prescribing hurdles
- Limited differentiation from SAOs and other ROOs
- Limited dose range versus other ROOs
- Access to product outside typical retail channels (hospice, LTC institutions)

Opportunities

- Increased noise by new market entry may raise awareness/treatment of BTP with ROOs
- Large gap between ROO-eligible and ROO-treated patients
- Improved HCP/patient dialogue increases BTP/ROO treatment rates in BTP
- Stronger BTP/ROO recommendations in chronic pain guidelines

Threats

- BTP alternatives (eg, LAOs/SAOs) have less stringent/no REMS requirements
- New competitors: Onsolis and Abstral
- MCO pressures on premium-priced products
- Patient refusals due to out-of-pocket costs
- Miscommunication between HCPs and patients regarding BTP

[a] PDUFA date for sublingual administration is anticipated December 2009.

Key Issues

1. The clinically meaningful value of a ROO/*FENTORA* is not seen by HCPs

The ROO clinical profile, fast onset of action and limited duration, is ideally suited for the management of BTP. Most physicians manage BTP with monotherapy, LAOs/SAOs, or a combination of LAO plus SAO. Physicians' extensive experience and comfort level with traditional onset SAOs has limited their adoption of ROOs, and the small number that have used a ROO as third- or fourth-line treatment. Compelling evidence to drive a change in physician behavior is sparse; there are no robust published clinical studies demonstrating the value of a ROO versus traditional SAOs. Additionally, there are no established BTP treatment guidelines.

A significant contributing factor to why prescribers minimize the value of a ROO is due to the fact that prescribers may not fully appreciate the impact BTP has on a patient's ability to maintain a "normal" day-to-day routine.

Contributing to this issue is the prescriber/patient BTP dialogue. Market research has identified a distinct disconnect in the language used by both the prescriber and the patient when discussing BTP. Physicians communicate and assess in terms of pain scales ("better/worse" or "10 vs 9"); in doing this the prescriber's goal is to cover the patient's BTP by increasing their LAO or SAO, and leading to the potential effects of overmedication (ie, somnolence). Conversely, patients communicate their BTP with necessary daily activities (ie, "I can still walk") or qualitatively ("it shoots/burns/stabs"). Treatment goals are typically associated with the patients' individualized needs and lifestyles.

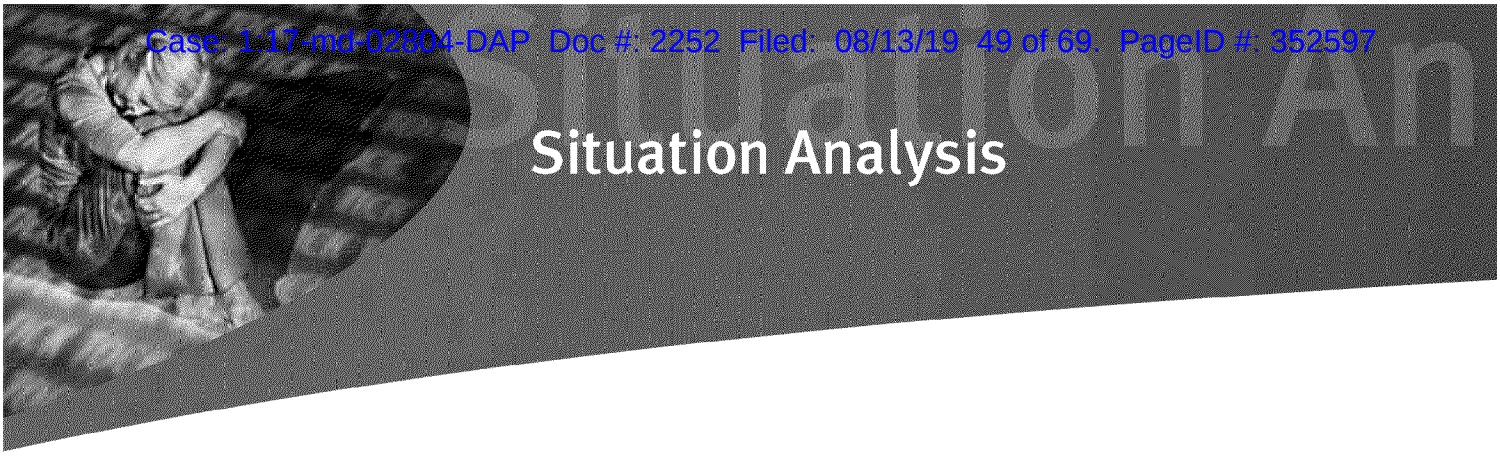
2. Multiple barriers to writing *FENTORA* perceived by HCPs

Current users indicate that *FENTORA* requires a high level of commitment in terms of patient selection, educating patients on proper dosing, and managing the reimbursement process.

The majority of managed care plans require a PA for *FENTORA* coverage. The PA requirements vary by plan, but typically include use for labeled indication, step edits, and letters of medical necessity. Plans also place quantity restrictions on *FENTORA* prescriptions.

Another barrier is prescriber concerns of abuse, addiction, and diversion, as well as scrutiny of regulators that monitor the prescribing and dispensing of class-II opioids.

Patients are also reluctant to use *FENTORA* due to the cost of their copay, the stigma of opioid use, and the fear of addiction.



Situation Analysis

3. Limited opioid REMS awareness, acceptance, and endorsement by HCPs

Through a variety of market research, Cephalon has gained key insights regarding the pending REMS requirements for opioids, as well as for the *FENTORA* SECURE Access Program (REMS). The research provided findings that, in general, customer opinion has not been favorable for REMS. While the concept of REMS has become more familiar in 2009, the prescriber base is not overly savvy to the FDA opioid REMS requirements.

Historically, when prescribers have been tasked with incorporating a REMS program into their day-to-day practice, they view them as burdensome and overly time-consuming. However, prescribers were willing to incorporate the process into the workflow given that the therapeutic agent to be used was likely an agent of "last resort" or an end stage option. This is quite the opposite when considering a ROO REMS.

The primary issue from a stakeholder's perspective with a ROO being mandated into a REMS program is that the prescriber has other options (ie, SAOs) to utilize for BTP treatment. These options currently do not have a REMS program and would not be a burden to their practice flow, have barriers to prescribing the drug, or increase their liability when prescribing opioid analgesics.

Logistical Prescriber Concerns	Liability Prescriber Concerns
Inconvenient/additional work	Intrusion/excessive oversight
Time drain/time consuming	Privacy/confidentiality concerns
Inconvenience/hassle factor	Legal liability shift tied to enrollment language
Barrier to prescribing drug	
Additional non-billable time/cost to comply	

Initial acceptance of this program will be a challenge. Prescribers will need a significant amount of education and reinforcement around the value a REMS program will offer.

Although customer perception and concerns over REMS programs exist among prescribers, pharmacies, and physician and patient advocacy groups, the regulatory body is adamant in moving forward with the implementation of class-wide opioid REMS because of the issues around misuse, abuse, and diversion.

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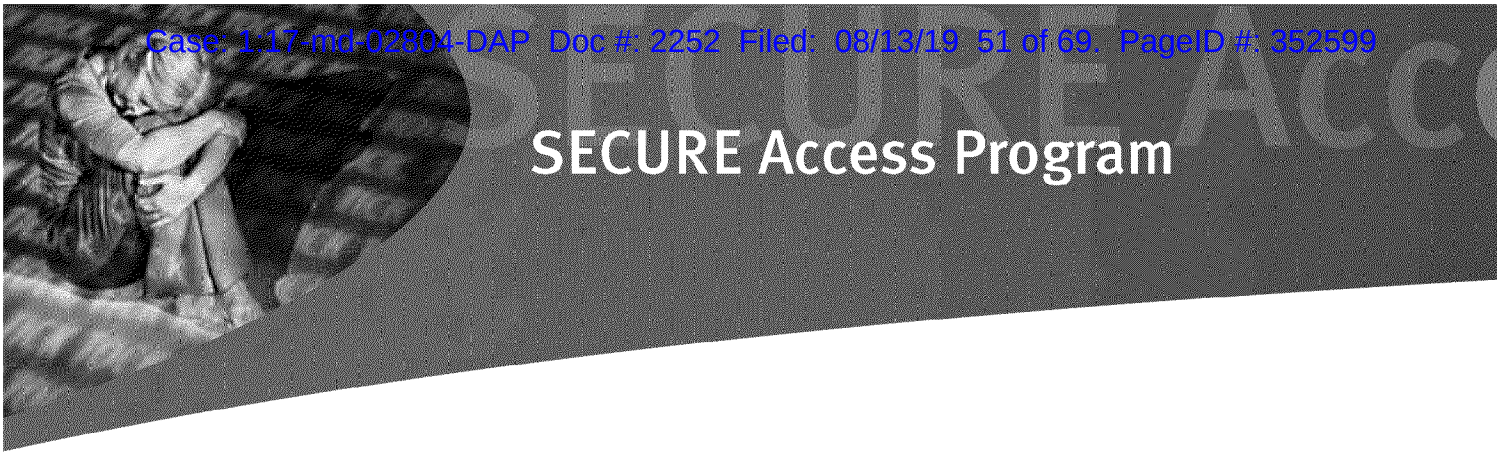


FENTORA SECURE Access Program

The SECURE Access Program will be the second REMS program to be executed for the ROO class. This program is an extension of the SECURE (Solutions through Education, Communication & Understanding of Risk minimization Excellence) program, the overarching risk minimization plan for *FENTORA*. The other ROO REMS is the Onsolis FOCUS program, which was approved and launched October 2009. The FOCUS program only allows access to Onsolis through a specialty pharmacy distribution system.

The SECURE Access Program is designed to ensure safe and appropriate use of *FENTORA*. Because of FDA requirements, the SECURE Access Program has similarities to the other ROO REMS. However, a key difference between the 2 programs is that the *FENTORA* program provides access to the medication through retail pharmacies. This is an important difference as ~92% of *FENTORA* prescriptions are distributed through retail segments. Therefore, key stakeholders for *FENTORA*, those typically associated with most retail products—specifically prescribers, their staff, patients, and pharmacies— would not experience major disruptions to the prescribing and dispensing of *FENTORA*.

Cephalon believes that the design of the SECURE Access Program would:

- Educate prescribers on appropriate patient selection (opioid tolerant patients)
- Minimize the burden to key stakeholders
- Maximize education and communication between the HCP and patient
- Maintain appropriate patient access to *FENTORA*

It is important to understand that even with retail access to *FENTORA*, the REMS program presents challenges to Cephalon and our stakeholders.

The following are key challenges associated with the *FENTORA* REMS:

Currently, post-marketing surveillance and secondary data analyses estimate that ~20% of patients on *FENTORA* may not meet the strict definition of opioid tolerance as defined in the label and would, therefore, be prohibited from participating in the program.

The REMS will require additional actions beyond the typical retail prescribing process. If the process is overly burdensome and other opioids used for BTP are not required to have a REMS, prescribers and patients may choose not to participate and instead select the alternative BTP therapies. Alternative BTP treatment options may cause a "Balloon Squeeze" effect, which could potentially push or "squeeze" more prescriptions toward non-REMS opioids. This effect would not serve public health, because users and abusers may shift to unrestricted/less restrictive opioids (ie, SAOs).

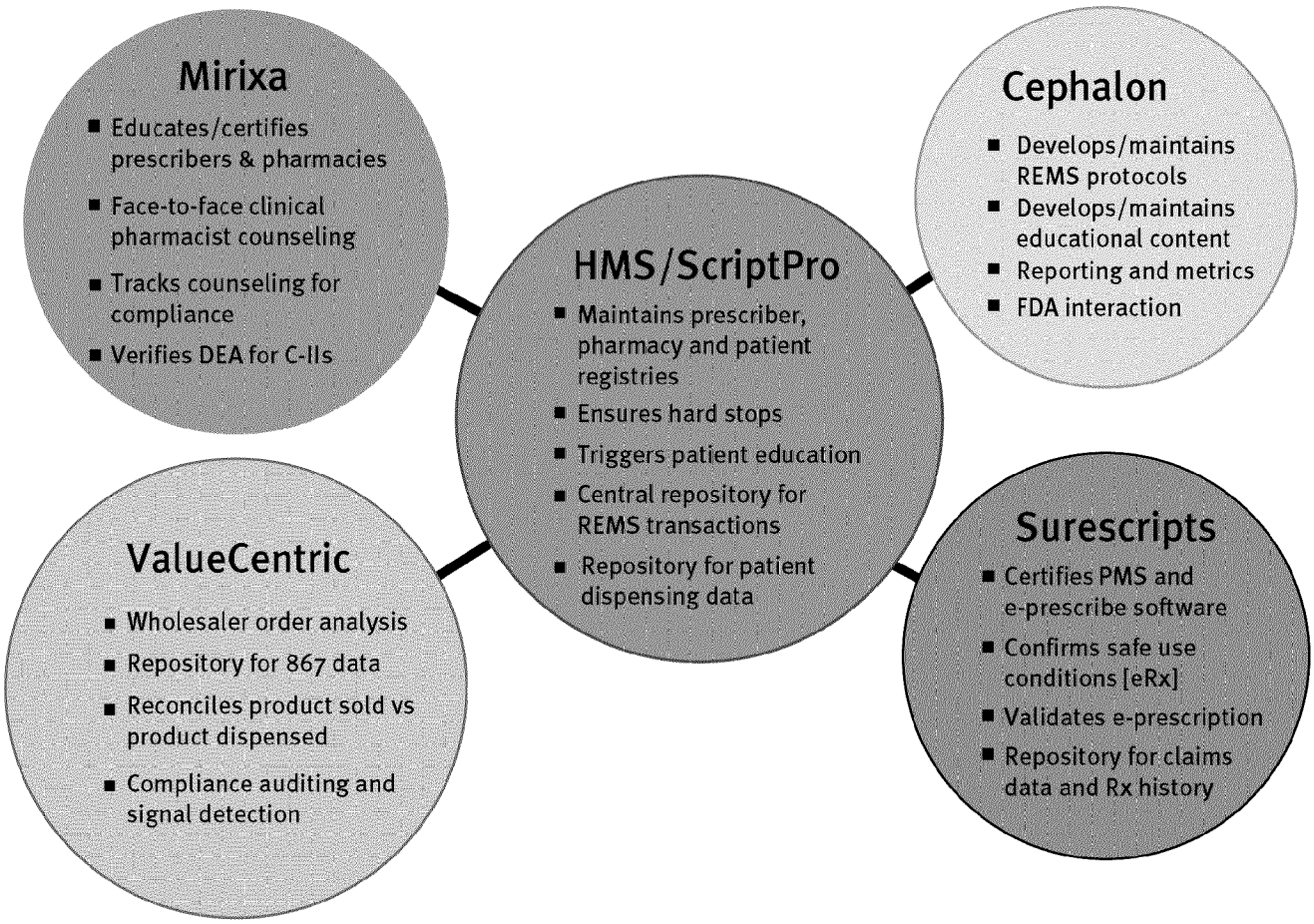
Approval of the expanded label is contingent upon documenting the effectiveness of the REMS.

SECURE Access Program

SECURE Access Program Overview[a]

The SECURE Access Program is:

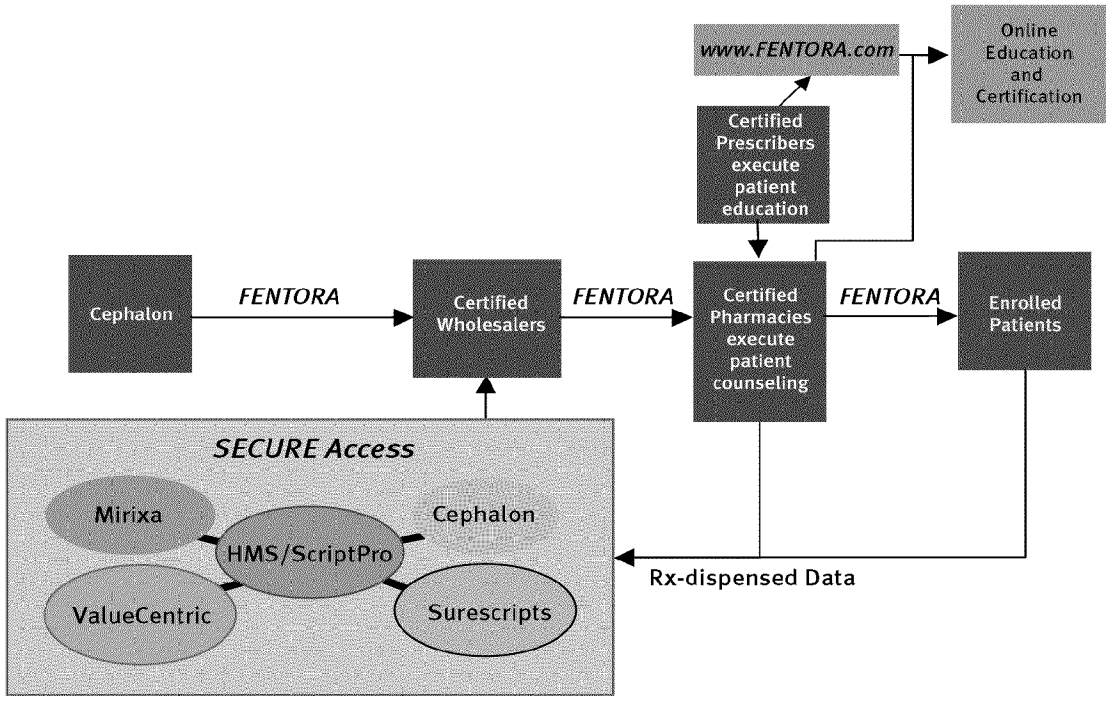
- A program designed to provide controlled access to *FENTORA* for appropriate patients
- A collaboration of established healthcare services organizations, including HMS/Cephalon, ScriptPro, Surescripts, Mirixa, and ValueCentric
- An integrated end-to-end secure solution utilizing existing technology within the current workflow practices



[a] The SECURE Access Program is currently under development and has not been finalized. Program is subject to review and approval by the FDA.

SECURE Access Operational Model[a]

The SECURE Access Program is designed to ensure safe and appropriate access to *FENTORA*. The schematic below represents the closed-system model of the SECURE Access Program.



[a] This model represents e-prescribing without class II approval.

The program requires stakeholders to enroll and maintain enrollment in the system in order to have access to *FENTORA*. The criteria for each stakeholder are the following:

- Wholesalers/distributors agree to ship *FENTORA* only to certified pharmacies
- Pharmacies complete education requirements and agree to implement the program requirements
- Prescribers complete the certification requirements and agree to implement the program requirements
- Patients consent to education/counseling and agree to program requirements by signing a Prescriber-Patient Agreement

Additionally, there is a mechanism within this model to identify and inactivate stakeholders who have lost eligibility.

Business Strategy

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Business Strategy

Overall Business Strategy

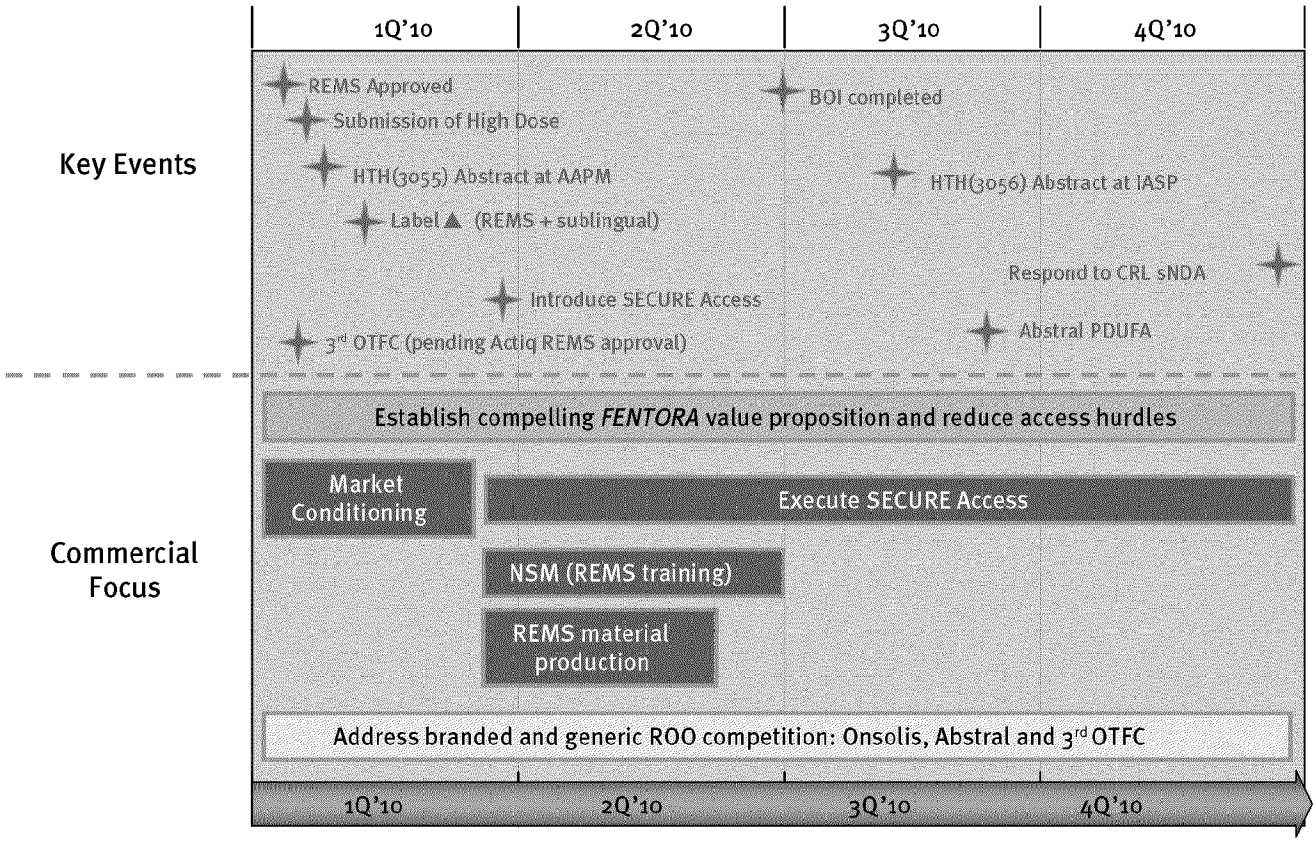
In 2010, the strategy for *FENTORA* is to rebuild its foundation through differentiation from SAOs and other ROOs, minimizing the reimbursement barriers, and ensuring the successful implementation of the SECURE Access Program. Personal promotion will focus on ~1500 opioid prescribers. Nonpersonal promotion will focus on the entire targeted universe (~7300).

Strategic Statement

Enhance prescriber understanding of the value *FENTORA* offers to opioid tolerant patients with BTP, motivating prescribers to address payer access hassles and enroll/participate in SECURE access.

Timeline Assumptions

The schematic below outlines the timeline assumptions used to build this brand plan. These assumptions are subject to change because of uncertainties surrounding regulatory issues and the timing of new market entries.



Business Strategy

Key Strategic Imperatives and Substrategies

The 2010 marketing objectives are to differentiate *FENTORA* from other ROOs and SAOs, to flawlessly implement the SECURE Access program, and to minimize the barriers to appropriate patient access and use. These objectives are dependent upon timeline assumptions and key events. Resources will be adjusted to ensure the success of priority strategies and tactics.

The key strategic imperatives (KSI), strategies, and the high level tactical overview to achieve these objectives are the following:

KSI 1: Differentiate With a Compelling Value Proposition	
• Ensure that prescribers recognize *FENTORA* is an ideal option for appropriate patients with cancer who are suffering from BTP episodes because *FENTORA* matches the temporal characteristics of BTP	
Strategy	**Tactics[a]**
Enhance HCP/patient dialogue	• Develop prescriber communication workshops to bridge the prescriber-patient gap when discussing BTP ("Voices & Faces of Pain") • Create patient case studies • Develop tools to enhance the prescriber-patient BTP dialogue (ie, "BTP Education Station")
Establish functionality as benefit of appropriate BTP treatment	• Conduct media outreach to highlight data announcements on the body of evidence around burden of illness **Prescribers** • Develop educational materials to educate on disease awareness that incorporate HCP feedback —Prescriber discussion guide • Develop non-branded educational components that address barriers in assessment and treatment of BTP —"ROO Tube" – a video dialoging tool that displays sample dialogues between HCPs and patients **Patients & Caregivers** • Provide venues and materials for patient education —ShareYourPain.org • Create patient/caregiver-focused BTP podcast series to raise awareness of cancer-related BTP and treatment options
Differentiate *FENTORA* from SAOs/ROOs	• Create appropriate resources to communicate the body of evidence on *FENTORA* over other ROOs • Evolve the current patient-centric campaign imagery (launched 6/09) to show *FENTORA* as the "solution" to BTP in opioid tolerant patients with cancer • Streamline the messaging – Patient, Problem, Solution • Sustain strong personal and non-personal SOV vs competitor

[a] The tactics represented are intended only to provide an overview of recommendations.

KSI 2: Reduce Barriers to *FENTORA* Treatment	
• Reinvigorate the prescriber's willingness to navigate the reimbursement process so that appropriate patients have access to *FENTORA* • Ensure that Managed Care recognizes the value of *FENTORA* for select patients	
Strategy	**Tactics**[a]
Elevate importance of appropriate treatment and outcomes to all stakeholders	• Create appropriate resources to communicate clinical data to educate MCOs on *FENTORA* and why it is the optimal treatment for BTP —Dossier —NAM slide presentation on BTP, ROOs, *FENTORA*, and REMS • Develop and implement clinical presentation for MSLs/MDs with head-to-head data
Enhance reimbursement support	• Enhance *FENTORA* Assistance Card Program using web-based ordering and targeted e-mail to provide prescriber ability to order cards according to individual needs —Card provides important safety messages —Defrays patient copay at point of dispensing • Update the voucher program to work in concert with the *FENTORA* Assistance Card • Develop comprehensive reimbursement kits • Initiate Virtual Practice Manager Programs (pending internal review)
Segment payer market to drive targeted efforts	• Selectively contract with MCO • Develop and implement defense plan against Onsolis

[a] The tactics represented are intended only to provide an overview of recommendations.

Business Strategy

KSI 3: Flawlessly Execute SECURE Access	
Strategy	**Tactics[a]**
Drive positive perception and early enrollment	• Condition market on REMS —KOL "REMS Awareness" program • Convention presence ("Ready for REMS") —Building awareness in advocacy groups • Develop simple education and enrollment materials and tools for prescribers, office staff, and pharmacists • Develop supplemental resources that educate, motivate, and reinforce the benefit of the SECURE Access program • Communicate corporate commitment to safety —Continue to educate on the importance of appropriate patient selection in all promotional programs and material —Continue to educate on the safe use of *FENTORA* in all promotional programs and materials • Create an efficient method to provide education to all stakeholders (internal and external) — Develop a comprehensive training plan for field force • Develop multi-venue–based training for targeted audience (~6000 HCP)
Execute training appropriate to each stakeholder	• Create a prescriber feedback program • Develop office staff resources for patient outreach • Provide field force tools for communication to customers on: —SECURE Access: Prescriber Experience Programs • Develop/reinforce resources to encourage ongoing stakeholder participation
Generate program advocacy	• Create a prescriber feedback program • Develop office staff resources for patient outreach • Provide field force tools for communication to customers on: —SECURE Access: Prescriber Experience Programs • Develop/reinforce resources to encourage ongoing stakeholder participation

[a] The tactics represented are intended only to provide an overview of recommendations.

Resource Allocation

Targets	Description	Sales Force	NAMs	Non-personal	Investment	Major Focus
Prescribers[a]	Core 102 Dec 8-10	√		√	+++	• Enhance value of *FENTORA* • Decrease BTP communication gap • SECURE Access
	Users 346 Dec 5-7	√		√	+++	• Enhance value of *FENTORA* • Decrease BTP communication gap • SECURE Access
	Body 998 Dec 2-4	√		√	+++	• Enhance value of *FENTORA* • Decrease BTP communication gap • SECURE Access
	Trialers 1,554 Dec 1	√		√	++	• Increase understanding of BTP and establish value of *FENTORA* • SECURE Access
	Non-writers ~4300 Dec ø			√	++	• Increase understanding of BTP and reestablish *FENTORA* as therapeutic option • SECURE Access
	ROO ~5000			√	+	• Increase understanding of BTP • Decrease BTP communication gap • Drive trial and usage • SECURE Access
Pharmacies	Retail based ~15,000	√		√	+++	• SECURE Access
Patients	Opioid tolerant w/ BTP			√	+	• Decrease BTP communication gap • SECURE Access
Payers	MCOs		√		+	• Patient access to *FENTORA* • Increase understanding of BTP and establish value of *FENTORA* • SECURE Access

[a] Prescriber Feb 2009-July 2009.

Business Strategy

Messaging Strategy

In 2010, the *FENTORA* messaging will be reevaluated to ensure that it is concise and resonates with the target audience. Messaging will continue to focus on product strengths of *FENTORA* for the treatment of BTP in patients with cancer. Key messaging will evolve to emphasize the onset and duration of effect in relation to a typical BTP episode and the potential for positive outcomes in appropriate opioid tolerant patients with cancer and BTP.

Sales Force Strategy

In 2010, the targeted reach and frequency will be reevaluated to ensure that the appropriate productive prescribers are being targeted and detailed on *FENTORA* in order to establish and reinforce its position as preferred treatment of BTP in opioid tolerant patients with cancer. Messages will continue to provide important safety and dosing information in an effective manner that resonates with our prescribers.

In 2010, the *FENTORA* field force will need to focus on promotional efforts on targeted prescribers **Redaction - Other Teva Product** AMRIX. The field force will need to communicate key messages around:

- Efficacy and the meaningful value *FENTORA* may provide in the treatment of BTP in patients with cancer
- Appropriate patient selection
- Risk minimization

Additionally, the field force will be an integral part of ensuring enrollment of targeted prescribers and pharmacies in the SECURE Access Program. A reevaluation of weighting must occur, as there will be increased time needed for stakeholder education and enrollment during the launch period.

Clinical Strategy

FENTORA has a robust clinical profile. The foundation of this was established from a unique pharmacokinetic (PK) profile, as well as from efficacy and long-term safety data for the current approved indication. For 2010, there are additional trials designed to be supportive of the brand's stated KSIs.

FENTORA—Clinical Development

Study/sponsor	Study Design	Estimated Completion Date
FBT – 3056/Clinical Research	DB, Crossover - FBT vs Oxy IR (similar to Study 3055); followed by 12-week OL	Jan 2010
Phase IV - Validation Study/Medical Affairs	Validation of three exploratory assessments (CAPF, PAF, and GAS)[a] used in the noncancer BTP Study 3052	Jan 2010
Phase IV - BTP Burden of Illness/Medical Affairs	Epidemiology and Burden of Illness – BTP in opioid tolerant patients with chronic cancer and noncancer pain	June 2010

[a] CAPF=Clinical Assessment of Patient Function; PAF=Patient Assessment of Function; GAS=Goal Attainment Scale.

Business Strategy

Regulatory Strategy

The regulatory deliverables of gaining approved REMS is important as it will help to ensure safe and appropriate use of *FENTORA*. Additionally, the other actions listed below will be supportive of the brand's efforts in differentiating *FENTORA* from other SAOs and ROOs.

FENTORA—Clinical Development

Deliverable	Actions	Estimated Completion Date
Incorporate date from sublingual study into labeling	Submit data from study 1043 to FDA (S-008); FDA PDUFA action date	PDUFA Action date: 12/31/09
Obtain FDA-approved REMS	Submit 9/14/09 Negotiation in progress with FDA	Anticipate approval: Q1
Increase available strengths of *FENTORA* to product line to provide patients with greater dose options	Submit data from PK BE study and labeling after approval of REMS Anticipate FDA warranting clinical safety data obtained before approving high dose	**TBD**

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Financials

2010 Financial Objectives

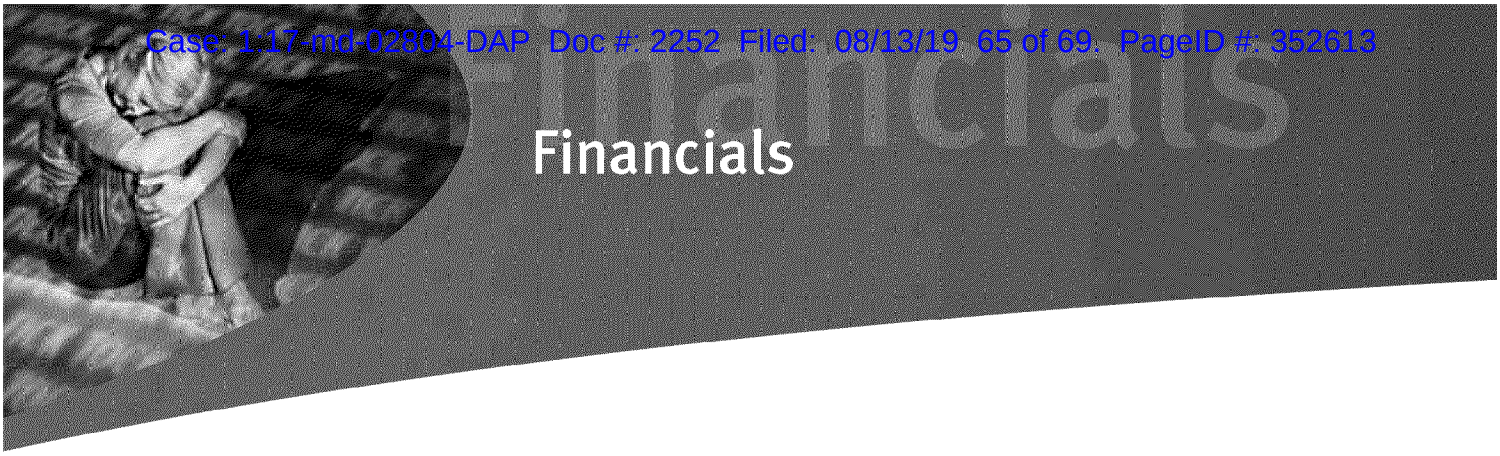
Total Revenue: $140MM
TRxs: ~48,000
TRx Exit Share: 25%

Assumptions

- SECURE Access approved as submitted
- Retail pharmacy distribution
- *FENTORA* prescribing impacted by REMS
- Opioid non-tolerant patients excluded (~20%)
- Opioid class follow similar/same REMS requirements
- SECURE Access investment leveraged for success

Challenges to Assumptions

- REMS impact
  - Process disruption from program
  - Prescribing shifts to alternative opioids that do not have the burdensome perception of a REMS program
  - Loss from patients not meeting opioid tolerant criteria (~20%)
- Competitive impact
  - Increased voice in BTP market
  - High-dose advantage over *FENTORA* (2010)
  - Specialty pharmacy distribution



Marketing Budget

Category	2010	Description/Business Activity
A&P	$5,075	Personal, nonpersonal, and Web initiatives to change beliefs around ROOs and to differentiate and increase utilization of *FENTORA*
CSPs	$3,000	Utilized for *FENTORA* education as well as REMS education and enrollment as appropriate
Market research	$820	
Med ed	$400	Ad boards, speaker training, consultant meetings
Conventions	$600	
PR	$1,000	
Reprints	$200	
Vouchers/debit cards	$2,650	Titrating and maintaining *FENTORA* patients
REMS	$6,255	Creating, producing, and fulfilling education module and enrollment materials, label change, outreach, and SECURE Web site updates and maintenance
Total Budget	**$20,000**	

Contribution

Category	2010 (MM)
Gross sales	$140.0
Marketing expense	$20.0 (REMS: $7; A&P: $13)
Sales	$13.2
CME/pubs/ISS	$3.9
Clinical trials	$0.9
Contribution	$102.0

FENTORA®
fentanyl buccal tablet

Terms, References, and Appendix

Glossary of Terms

AMFE: Area Marketing Field Effectiveness (manager)

BEMA: BioErodible MucoAdhesive technology used in Onsolis

BTP: Breakthrough Pain

KSI: Key Strategic Imperative

LAO: Long-Acting Opioid

OTFC: Oral Transmucosal Fentanyl Citrate

PCS: Pain Care Specialists

REMS: Risk Evaluation and Mitigation Strategy

ROO: Rapid-Onset Opioid

SAO: Short-Acting Opioid

SOV: Share of Voice

TSS: Territory Sales Specialists

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Terms, References, and Appendix

Key Clinical Studies

NDA		Published (Y/N)
99-14	Efficacy: CA BTP	Y
99-15	Safety: CA BTP (open label)	Y
1026-29	PK: 4 main studies	Y
sNDA:Expanded Label (noncancer)		
3040	Safety: all non-CA BTP (open label)	Y
3041	Efficacy: neuropathic BTP	Y
3042	Efficacy: lower back BTP	Y
3052	Pivotal Efficacy: all non-CA BTP	N[a]
3054	Pain anxiety symptoms	N
Other PK Studies		
1043	Buccal vs sublingual	Y
1052	High dose	N[a]
1046	Relative potency (IV morphine)	N[a]
H-2-H Studies		
3055	vs OxyIR ST efficacy & safety	N
3056	vs OxyIR LT efficacy & safety	N[b]

[a] 3052, 1052, and 1046 are published in abstracts only as of 2009.
[b] Study data available ~ April 2010.

Terms, References, and Appendix

2010 *Fentora* Convention Schedule

Convention	Date	Audience Profile/ Attendance	Exhibit Space
AAPM - American Academy of Pain Medicine[a] San Antonio, TX (Corporate Members)	2/03-2/05	Pain Specialists 900	30 X 30
AMCP - Academy of Managed Care Pharmacy[b] San Diego, CA (Managed Care Meeting)	4/07-4/10	Pharmacists 5000	10 X 20
APS - American Pain Society[a] Baltimore, MD (Corporate Members)	5/06-5/07	Pain Researchers 1500	30 X 30
ONS - Oncology Nursing Society San Diego, CA	5/13-5/16	Oncology Nurses 5500	20 X 20
2010 PAIN WEEK Las Vegas, NV	9/08-9/12	Pain Specialist 800	10 X 20
AAPM - American Academy of Pain Management Las Vegas, NV (Corporate Members)	9/21-9/24	Pain Management 1000	10 X 20
ASA - American Society of Anesthesiologists San Diego, CA	10/18-10/20	Anesthesiologists 16,000	20 X 20

Redaction - Other Teva Product AMRIX.

Redaction - Other Teva Product AMRIX and NUVIGIL.